INSTRUCTIONS FOR USE FOR:

GORE

TAG®

THORACIC
ENDOPROSTHESIS

CONFORMABLE

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English

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INSTRUCTIONS FOR USE

GORE® TAG® Thoracic Endoprosthesis

- **CAUTION – USA Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**
- **Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.**

DESCRIPTION

The GORE® TAG® Thoracic Endoprosthesis provides endovascular repair of isolated lesions of the descending thoracic aorta (DTA). The GORE® TAG® Thoracic Endoprosthesis may be used as a single device or in multiple device combinations to accommodate the intended treatment site.

This device is a flexible, self-expanding endoprosthesis that is constrained on the leading end of a delivery catheter. The system consists of two parts, the endoprosthesis and the delivery catheter (**Figures 1 and 2**). Endoprosthesis sizes range in diameter from 21 to 45 mm and in length from 10 to 20 cm (**Table 67**). The compressed profile of these devices on a delivery catheter ranges from 18 to 24 Fr.

The endoprosthesis consists of an ePTFE/FEP graft supported over its entire length by a nitinol wire frame (stent). A radiopaque gold band is embedded in the graft material at each end for device imaging. The stent is attached to the external surface of the graft by laminated ePTFE / FEP bonding tape. The proximal end of the endoprosthesis (stent graft) consists of exposed stent apices, while the distal end of the stent is in line with the graft material. An ePTFE sealing cuff is attached over the stent to each end. For delivery, the endoprosthesis is mounted onto the delivery system.

Table 1. GORE® TAG® Thoracic Endoprosthesis Materials

Materials
ePTFE (polytetrafluoroethylene)
FEP (fluoroethylpropylene)
Nitinol (Nickel, Titanium)
Gold

The delivery system consists of a catheter and a sewn deployment sleeve. The catheter is compatible with a 0.035" or smaller guidewire. Leading and trailing olives longitudinally restrain and protect the endoprosthesis during introduction. The leading olive contains a radiopaque marker band and a radiopaque soft tip to facilitate device placement. The trailing olive is constructed using a radiopaque material to facilitate device placement. The endoprosthesis is constrained by the sewn deployment sleeve and is mounted on the leading end of the catheter. Pulling the deployment knob, which is attached to the deployment line system, unlaces the sleeve from the center out and allows the self-expanding endoprosthesis to deploy. The sleeve is secured to the stent graft and remains implanted between the endoprosthesis and the vessel wall.

The GORE® TAG® Thoracic Endoprosthesis is compatible with either the GORE® DrySeal Sheath or the GORE® Introducer Sheath with Silicone Pinch Valve. Two device introducer sheath caps (hemostasis caps) are included with the GORE® TAG® Thoracic Endoprosthesis. The device introducer sheath cap is to be attached to the trailing end of the GORE® Introducer Sheath with Silicone Pinch Valve to provide a seal between the sheath and the GORE® TAG® Thoracic Endoprosthesis and the GORE® Tri-Lobe Balloon Catheter. Refer to the GORE® Introducer Sheath with Silicone Pinch Valve Instructions for Use for more information. These caps are only to be used with the GORE® Introducer Sheath with Silicone Pinch Valve. They are NOT compatible with the GORE® DrySeal Sheath.

Figure 1. GORE® TAG® Thoracic Endoprosthesis

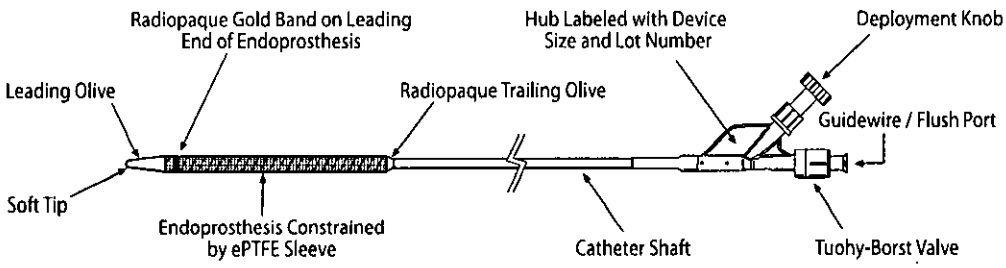
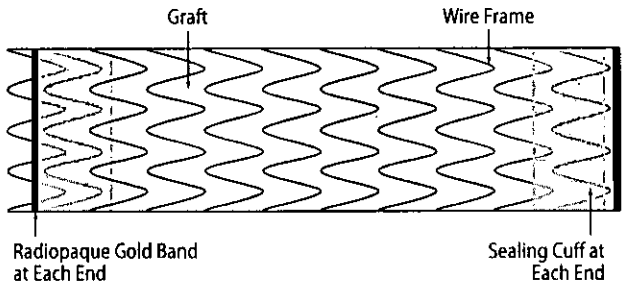


Figure 2. Deployed GORE® TAG® Thoracic Endoprosthesis



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INDICATIONS FOR USE

The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of isolated lesions (not including dissections) of the descending thoracic aorta in patients who have appropriate anatomy, including:

- Adequate iliac / femoral access
- Aortic inner diameter in the range of 16-42 mm
- ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion

CONTRAINDICATIONS

The GORE® TAG® Thoracic Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials (**Table 1**)
- Patients who have a condition that threatens to infect the graft

WARNINGS AND PRECAUTIONS

General

- Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences, injury to the patient or death. Compliance with device sizing recommendations is critical to optimal performance of the device.
- Read all instructions carefully, particularly the following sections: **Table 67**: SIZING GUIDE, and in the DIRECTIONS FOR USE: *Anatomical Requirements*, and *Using Multiple Devices*.
- The long-term performance of stent grafts has not been established. All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging lesions) should receive enhanced follow-up (See IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- The safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis to treat traumatic aortic transections was determined based on 30 day follow-up data. Due to the short-term nature of this data, all patients should be advised that long-term, regular follow-up is necessary to assess patients' health status and stent graft performance.
- The GORE® TAG® Thoracic Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre and post-operative imaging and follow-up described in IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP. The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The GORE® TAG® Thoracic Endoprosthesis is only compatible with the GORE® Introducer Sheath with Silicone Pinch Valve or the GORE® DrySeal Sheath. Compatibility with other sheaths has not been established. If an incompatible introducer sheath is used, damage may occur to the endoprosthesis, delivery system, or catheter, which may cause premature or inadvertent deployment, or breakage. Please refer to specific sheath IFU for instructions for use.
- *In vitro* testing has shown that the GORE® TAG® Thoracic Endoprosthesis is not compatible with introducer sheaths that have multi-layer silicone disc valves. Catheter breakage has been observed in clinical use with such valves.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging lesions and / or endoleak. An increase in lesion size and / or persistent endoleak may lead to lesion rupture.
- Always have an appropriate surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

Patient Selection and Treatment

- Successful patient selection requires specific imaging and accurate measurements; please see *Measurement Techniques and Imaging* section below.
- The GORE® TAG® Thoracic Endoprosthesis is designed to treat aortic neck diameters no smaller than 16 mm and no larger than 42 mm. The GORE® TAG® Thoracic Endoprosthesis is designed to treat proximal and distal aortic neck lengths no less than 20 mm distal to either the left subclavian or left common carotid artery. Additional proximal aortic neck length may be gained by covering the left subclavian artery (with or without discretionary transposition or bypass) when necessary to optimize device fixation and maximize aortic neck length. Distal aortic neck length of at least 20 mm proximal to the celiac axis is required. These sizing measurements are critical to the performance of the endovascular repair.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy and disease state, is required to assure successful sheath introduction and subsequent withdrawal. A surgically created vascular conduit may be needed to achieve access in select patients.
- The safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis have not been evaluated in the following patient etiologies:
  - acute and chronic dissections
  - aortic fistulas
  - aortotitis or inflammatory aneurysms
  - intramural hematoma
  - mycotic aneurysms
  - penetrating ulcers
  - previous stent or stent graft or previous surgical repair in the descending thoracic aortic area
  - pseudoaneurysms resulting from previous graft placement
  - genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome)
  - patients with active systemic infections
  - patients less than 21 years old
  - pregnant or nursing females
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (**Table 67**) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.
- All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intra-operative flexibility to achieve optimal procedural outcomes.
- Ilio-femoral access vessel size and morphology (e.g., minimal thrombus, calcium and / or tortuosity) should be adequate to accommodate the required introducer sheath diameters (**Table 67**) using appropriate vascular access techniques (including surgical conduit, if needed).
- Key anatomic elements that may affect successful exclusion of the lesion include severe neck angulation, short aortic neck(s) and significant thrombus and / or calcium at the arterial implantation sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation.
- Excessive thrombus or atherosclerotic plaque in the aortic arch may increase the risk of stroke secondary to the implantation procedure.

- Use of the GORE® TAG® Thoracic Endoprosthesis outside of the recommended anatomical sizing guidelines (**Table 67**) may result in potentially serious device-related events (e.g., device infolding, excessive device compression, endoleak, wire fracture, migration).
- If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the left subclavian artery should be considered.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The GORE® TAG® Thoracic Endoprosthesis is not recommended in patients with known sensitivities or allergies to ePTFE, FEP, nickel, or titanium.
- ASA risk was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01, TAG 03-03, and TAG 08-03 Aneurysm studies. Patients presenting with ruptured aneurysm may be at higher risk for complications associated with general anesthesia.

Measurement Techniques and Imaging

Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography (CTA) with 3-D reconstruction is the required imaging modality to accurately assess patient anatomy prior to treatment for the GORE® TAG® Thoracic Endoprosthesis. If contrast-enhanced spiral CTA with 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities. Clinicians recommend positioning of the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.

- Diameter
  A contrast-enhanced spiral CTA is required for aortic diameter measurements. Diameter measurements must be of the flow lumen not including vessel wall. The spiral CTA scan must include the great vessels through the femoral heads at an axial slice thickness of 3 mm or less.
- Length
  Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Thoracic Endoprosthesis. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Device Selection:

- Non-aneurysmal proximal and distal neck lengths of at least 20 mm are required. If aortic angulation is less than 60°, or if there is significant calcium or thrombus, additional neck length may be required.
- Strict adherence to the GORE® TAG® Thoracic Endoprosthesis IFU sizing guide is required when selecting the appropriate device size (**Table 67**). The GORE® TAG® Thoracic Endoprosthesis is designed to be oversized from 6 to 33%. Appropriate device oversizing has been incorporated into the IFU sizing guide. Sizing outside of this range may result in endoleak, fracture, migration, device infolding, or compression.
- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.
- Follow the Instructions for Use recommendations carefully using the sizing guide (**Table 67**) and aortic screening measurements (**Figure 9**) included in the IFU.

Implant Procedure

- Appropriate procedural imaging is required to successfully position the GORE® TAG® Thoracic Endoprosthesis in the landing zone and to improve apposition to the aortic wall.
- Device apposition to the inner curve of the aortic arch should be confirmed with procedural fluoroscopy and non-contrast radiography. If device apposition is not complete, the use of ballooning and / or additional GORE® TAG® Device(s) has been reported by physicians to assure apposition of the GORE® TAG® Device to the aortic wall in the acute setting.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01, TAG 03-03, and TAG 08-03 Aneurysm studies. More than 2 cm of proximal and distal neck length may help reduce the incidence of endoleak in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Clinicians recommend positioning the image intensifier (C-arm) so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not rotate the delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the delivery catheter with device outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not continue advancement or retraction of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel, endoprosthesis, or delivery catheter damage may occur.
- Incorrect deployment or migration of the endoprosthesis may require endovascular or surgical intervention.
- Use caution if removing the undeployed endoprosthesis through the introducer sheath. Inadvertent endoprosthesis deployment may occur. If resistance is felt during removal of delivery catheter, stop and withdraw delivery catheter and introducer sheath together.
- Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal.
- Do not cross significant arterial branches which do not have collateral or protected perfusion to end organs or body structures. Vessel occlusion may occur.
- When using the GORE® Introducer Sheath with Silicone Pinch Valve, ensure that the pinch valve is not twisted, collapsed, or bent during advancing or withdrawing the delivery catheter. Device damage and / or delivery catheter breakage may occur.
- The GORE® TAG® Thoracic Endoprosthesis is only compatible with either the GORE® Introducer Sheath with Silicone Pinch Valve or the GORE® DrySeal Sheath. Compatibility with other sheaths has not been established. If an incompatible introducer sheath is used, damage may occur to the endoprosthesis, delivery system, or catheter, which may cause premature or inadvertent deployment, or breakage. Please refer to specific sheath IFU for instructions for use.
- *In vitro* testing has shown that the GORE® TAG® Thoracic Endoprosthesis is not compatible with introducer sheaths that have multi-layer silicone disc valves. Catheter breakage has been observed in clinical use with such valves.
- When catheters are in the body, manipulate only under fluoroscopic guidance.
- Gore recommends the GORE® Tri-Lobe Balloon Catheter for use with the GORE® TAG® Thoracic Endoprosthesis. Data is not available for use of other balloon catheters with the GORE® TAG® Thoracic Endoprosthesis. Follow the Instructions for Use supplied with the GORE® Tri-Lobe Balloon Catheter.
- Do not use the GORE® Tri-Lobe Balloon Catheter in patients with a history of aortic dissection.

- To avoid vessel trauma, do not over inflate the GORE® Tri-Lobe Balloon Catheter in relation to the diameter of the artery or the GORE® TAG® Thoracic Endoprosthesis.
- Do not inflate the GORE® Tri-Lobe Balloon Catheter in areas of significant calcified plaque. Balloon rupture and/or vessel damage may occur.
- Care should be taken not to balloon outside of the GORE® TAG® Thoracic Endoprosthesis. Ballooning native vessel could lead to vessel damage, rupture, or death.

Follow-Up

- Do not use the GORE® TAG® Thoracic Endoprosthesis in patients unable to undergo the necessary pre-operative and post-operative imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis.
- Wire fractures have been reported on this type of endoprosthesis and may be more likely to occur in conditions with excessive endoprosthesis oversizing, flexion, kinking, or bending with cardiac or respiratory cycles. Wire fractures may have clinical consequences which may include, but are not limited to endoleak, endoprosthesis migration, and / or adjacent tissue damage.
- A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.
- In patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm, reintervention with a GORE® TAG® Thoracic Endoprosthesis was performed in three (15%) subjects through one year post-treatment. All reinterventions were performed within seven days of the initial procedure to treat endoleak.
- The incidence of type I endoleak was higher in patients enrolled in the TAG 04-01 Ruptured Aneurysm Arm compared to patients enrolled in the TAG 99-01, TAG 03-03, and TAG 08-03 Aneurysm studies. Additional radiologic follow-up may be warranted in patients who undergo endovascular repair for ruptured aortic aneurysm.
- Although the available data from use of the GORE® TAG® Thoracic Endoprosthesis 45 mm device supports similar outcomes compared to patients treated with smaller sized GORE® TAG® Devices, it is possible that patients with large aortic diameters represent a population for whom the aorta at that level is already diseased. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient; patients with larger aortic diameters may represent a population for whom additional regular follow-up is warranted. Regular and consistent follow-up is a critical part of ensuring the safety and efficacy of aortic endovascular repair.
- Non-clinical testing has demonstrated that the GORE® TAG® Thoracic Endoprosthesis is MR Conditional. Please refer to the IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP for MR information.

Potential Adverse Events

Complications associated with the use of the GORE® TAG® Thoracic Endoprosthesis may include but are not limited to:

access, delivery and deployment events (e.g. access failure; deployment difficulties/failures; failure to deliver the stent graft; and insertion or removal difficulty),
adynamic ileus,
allergic reaction (to contrast, anti-platelet therapy, stent graft material),
amputation,
anesthetic complications,
aneurysm expansion,
aneurysm rupture,
angina,
atelectasis / pneumonia,
bleeding (procedural and post-treatment),
bowel (e.g., ileus, transient ischemia, infarction, necrosis),
branch vessel occlusion,
cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension),
catheter breakage,
change in mental status,
coagulopathy,
contrast toxicity,
death,
dissection, perforation, or rupture of the aortic vessel & surrounding vasculature,
edema (e.g., leg),
embolism (micro and macro) with transient or permanent ischemia,
endoleak,
endoprosthesis: improper placement; incomplete deployment; migration; material failure; occlusion; infection; stent fracture; dilatation; perigraft flow,
erectile dysfunction,
erosion,
excessive or inappropriate radiation exposure,
femoral neuropathy,
fever and localized inflammation,
fistula (aortoeneteric, arteriovenous, aortoesophogeal, aortobronchial),
genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection),
hematoma,
infection (e.g., aneurysm, device or access sites),
lymphocele / lymph fistula,
myocardial infarction,
neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis),
nerve injury,
peripheral ischemia,
post-implant syndrome,
prosthesis dilatation / rupture,
prosthetic thrombosis,
pseudoaneurysm,
pulmonary complications (e.g., pneumonia, respiratory failure),
pulmonary embolism,
renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure),
reoperation,
restenosis,
surgical conversion,
thrombosis,
transient ischemic attack,
vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture),
wound (e.g., infection, dehiscence)

Device Related Adverse Event Reporting

Any adverse event involving the GORE® TAG® Thoracic Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call 800.437.8181. Outside the US, contact your local technical representative.

SUMMARY OF US CLINICAL STUDIES

A series of US clinical studies were conducted to evaluate the safety and effectiveness of the various versions of the GORE® TAG® Thoracic Endoprosthesis in aneurysm and traumatic aortic transection patient populations. A summary of these studies is provided below followed by study information and clinical data from each of the studies which supports the safety and effectiveness claims and the approved indications for use statement for the GORE® TAG® Thoracic Endoprosthesis. Two US clinical studies were conducted to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis in aneurysms of the descending thoracic aorta (DTA). The first, referred to as TAG 99-01, evaluated the original device design. The second US clinical study, referred to as TAG 03-03, evaluated a modified version of the device. TAG 99-01 and TAG 03-03 data are presented collectively. These data have been updated to reflect longer term follow-up that has become available since the original PMA and immediately follows. After approval of the GORE® TAG® Thoracic Endoprosthesis for treatment of aneurysms of the DTA, Gore conducted a third US clinical study, referred to as TAG 04-01, to evaluate the use of the modified device in ruptured aneurysms of the DTA. This data is presented subsequent to those data summarized in TAG 99-01 and TAG 03-03. In order to expand the treatment range from 23-37 mm to 23-42 mm diameter aortas, Gore conducted a fourth clinical study, TAG 06-02, to evaluate the use of the 45 mm GORE® TAG® Device for the repair of aneurysms of the DTA in subjects with aortas ranging from 37-42 mm. Data from this study follows the TAG 04-01 study data. Gore modified the GORE® TAG® Thoracic Endoprosthesis and conducted an additional study to evaluate this modified device. This fifth study, TAG 08-03, evaluated this modified version of the device for the treatment of aneurysms of the DTA with aortas ranging from 16-42 mm in diameter. Data from this study follows the TAG 06-02 study data. In order to expand the indications for use from aneurysms to isolated lesions of the DTA, excluding dissection, a sixth study, TAG 08-02, was conducted to evaluate the modified version of the device for the treatment of traumatic aortic transections of the DTA with aortas ranging from 16-42 mm in diameter. Data from this study follows the TAG 08-03 study data. This Instructions for Use contains the results of these US clinical studies.

Use of the GORE® TAG® Thoracic Endoprosthesis in Aneurysms of the Descending Thoracic Aorta: TAG 99-01 and TAG 03-03

TAG 99-01 Summary

TAG 99-01 was a non-randomized, multi-center clinical study designed to compare subjects treated with endovascular repair to an open surgical repair control group for repair of aneurysms of the DTA. The primary safety hypothesis was the proportion of subjects who experience one or more major complications will be less for subjects treated with the GORE® TAG® Thoracic Endoprosthesis (GORE® TAG® Device) than subjects treated with open surgical repair. The study design required 140 test subjects and 94 control subjects to test the study hypothesis with 80% power. The GORE® TAG® Device was considered effective if the aneurysm was excluded from blood flow in at least 80% of test subjects. Seventeen (17) US sites enrolled 140 GORE® TAG® Device and 94 Open Surgical Control subjects. GORE® TAG® Device and Open Surgical Control subjects were required to meet the same inclusion / exclusion criteria with the exception of the anatomical criteria required for endovascular repair. The control group included both historical (50) and concurrent (44) surgical subjects; an analysis showed comparability between the two groups of surgical control subjects.

Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1, 6, 12, 24, 36, 48, and 60 months post-treatment. Subject disposition and compliance is presented in **Table 2**.

An imaging core laboratory provided an independent assessment of the imaging data collected during this study. Site evaluation is also presented in this summary because the study hypotheses required an evaluation of the clinical significance of adverse events (i.e., major vs minor). Clinical events were adjudicated by a clinical events committee, and safety was monitored by a data safety monitoring board.

The primary objective of the study was to evaluate the safety and effectiveness of endovascular repair with the original GORE® TAG® Device as an alternative to open surgical repair. Safety was determined by comparing the proportion of subjects who experienced ≥ 1 major adverse event (MAE) through 12 months post-treatment between TAG 99-01 GORE® TAG® Device and TAG 99-01 Open Surgical Control subjects. Effectiveness was determined by evaluating the proportion of TAG 99-01 GORE® TAG® Device subjects free from a major device-related event through the 12 month follow-up visit in comparison to a predefined rate of success. Secondary objectives included an assessment of clinical benefit and quality-of-life measures. Enrollment began in September 1999 and was completed in May 2001. Annual follow-up through five years post-treatment was completed in 2006. The final study report was submitted in January 2007 and closed by the FDA in June 2007.

TAG 03-03 Summary

After completion of enrollment in TAG 99-01, breaks in the wire frame were identified. Modifications were made to the device to allow for removal of the component associated with the fractures. TAG 03-03 was designed to confirm that the modifications did not adversely affect the peri-operative (through 30 days) performance of the GORE® TAG® Thoracic Endoprosthesis.

The primary safety hypothesis was the proportion of subjects who experience one or more major complications through 30 days post-procedure will be less for subjects treated with the modified GORE® TAG® Device than for subjects treated with open surgical repair. The study design required at least 40 subjects to test the study hypothesis against the 94 surgical controls previously enrolled under the TAG 99-01 study with 81% power. The TAG 03-03 study enrolled 51 subjects who underwent endovascular repair at 11 investigational sites. The TAG 99-01 Open Surgical Control group served as the control. To support the comparability of the data between studies, the TAG 99-01 and TAG 03-03 studies used the same inclusion / exclusion criteria, screening assessments, clinical events committee, and imaging core laboratory. In addition, both studies collected identical study data (e.g., adverse events, device events).

Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1, 12, 24, 36, 48 and 60 months post-treatment. Subject disposition and compliance are presented in **Table 2**.

Safety was determined by comparing the proportion of subjects who experienced ≥ 1 MAE through 30 days post-treatment between TAG 03-03 GORE® TAG® Device subjects and TAG 99-01 Open Surgical Control subjects. Efficacy was the proportion of subjects who experienced ≥ 1 major device-related event in TAG 03-03 GORE® TAG® Device subjects through the 30 day follow-up visit. Efficacy data are presented descriptively. Secondary objectives included an assessment of clinical benefits and quality-of-life measures. Enrollment began in January 2004 and was completed in June 2004. Annual follow-up through five years post-treatment was completed in August 2009.

Table 2 provides the disposition and compliance for subjects enrolled into the TAG 99-01 and TAG 03-03 clinical studies. Available subjects are defined as those that are alive and participating in the study for that follow-up period. TAG 99-01 and TAG 03-03 subjects have all completed their fifth, and final, year of follow-up. For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit).

Table 2. Subject Disposition and Compliance by Study Period

		Follow-up Compliance			Events Prior to Next Interval		
Study Period	Eligible for follow-up[1]	Subjects with Visit in Window	CT Scan performed[2,3]	X-Ray performed[2,3]	Death[2]	Discontinued[2]	Not Due for Next F/U[2]
TAG 99-01 Open Surgical Control							
1 Month	94	93 (98.9%)	27 (28.7%)	72 (76.6%)	13 (13.8%)	0 (0.0%)	0 (0.0%)
6 Months	81	62 (76.5%)	18 (22.2%)	14 (17.3%)	6 (7.4%)	1 (1.2%)	0 (0.0%)
12 Months	74	54 (73.0%)	34 (45.9%)	8 (10.8%)	4 (5.4%)	1 (1.4%)	0 (0.0%)
24 Months	69	48 (69.6%)	27 (39.1%)	11 (15.9%)	5 (7.2%)	18 (26.1%)	0 (0.0%)
36 Months	46	29 (63.0%)	20 (43.5%)	2 (4.3%)	0 (0.0%)	6 (13.0%)	0 (0.0%)
48 Months	40	29 (72.5%)	21 (52.5%)	5 (12.5%)	2 (5.0%)	9 (22.5%)	0 (0.0%)
60 Months	29	24 (82.8%)	15 (51.7%)	4 (13.8%)	1 (3.4%)	1 (3.4%)	-
TAG 99-01 GORE® TAG® Device							
1 Month	140	140 (100.0%)	123 (87.9%)	130 (92.9%)	3 (2.1%)	3 (2.1%)	0 (0.0%)
6 Months	134	117 (87.3%)	108 (80.6%)	83 (61.9%)	16 (11.9%)	1 (0.7%)	0 (0.0%)
12 Months	117	111 (94.9%)	103 (88.0%)	88 (75.2%)	9 (7.7%)	6 (5.1%)	0 (0.0%)
24 Months	102	90 (88.2%)	80 (78.4%)	75 (73.5%)	8 (7.8%)	18 (17.6%)	0 (0.0%)
36 Months	76	68 (89.5%)	64 (84.2%)	58 (76.3%)	3 (3.9%)	4 (5.3%)	0 (0.0%)
48 Months	69	62 (89.9%)	57 (82.6%)	54 (78.3%)	6 (8.7%)	10 (14.5%)	0 (0.0%)
60 Months	53	52 (98.1%)	47 (88.7%)	43 (81.1%)	0 (0.0%)	3 (5.7%)	-
TAG 03-03 GORE® TAG® Device							
1 Month	51	51 (100.0%)	50 (98.0%)	51 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
6 Months	51	15 (29.4%)	14 (27.5%)	12 (23.5%)	2 (3.9%)	0 (0.0%)	0 (0.0%)
12 Months	49	46 (93.9%)	45 (91.8%)	42 (85.7%)	2 (4.1%)	1 (2.0%)	0 (0.0%)
24 Months	46	40 (87.0%)	36 (78.3%)	37 (80.4%)	5 (10.9%)	0 (0.0%)	0 (0.0%)
36 Months	41	35 (85.4%)	33 (80.5%)	28 (68.3%)	2 (4.9%)	1 (2.4%)	0 (0.0%)
48 Months	38	33 (86.8%)	29 (76.3%)	27 (71.1%)	7 (18.4%)	0 (0.0%)	0 (0.0%)
60 Months	31	24 (77.4%)	23 (74.2%)	19 (61.3%)	2 (6.5%)	5 (16.1%)	-

Study period definitions: 1 Month(0-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] Subjects are considered eligible for follow-up if time on the study is on or after the first day of the given time window and they have not discontinued or died prior to the start of the interval.

[2] Percentages are based on number of subjects eligible for follow-up. Compliance is based on site reported imaging assessments.

[3] Refer to individual results tables for the number of subjects with adequate imaging to assess the parameters provided in that specific results table.

Subject Characteristics

Tables 3-4 compare subjects receiving the GORE® TAG® Thoracic Endoprosthesis (TAG 99-01 and TAG 03-03) and Open Surgical Control subjects (TAG 99-01)

Table 3. Subject Demographics

	TAG 99-01 Control	TAG 99-01	TAG 03-03
Subjects Enrolled	**94**	**140**	**51**
Gender			
Male	48 (51.1%)	80 (57.1%)	33 (64.7%)
Female	46 (48.9%)	60 (42.9%)	18 (35.3%)
Age (yrs)			
n	94	140	51
Mean (Std Dev)	68.6 (10.2)	70.9 (10.4)	71.2 (9.4)
Median	70.1	74.2	71.5
Range	(35.2, 88.1)	(30.7, 86.5)	(45.0, 86.3)
Ethnic Background			
White or Caucasian	81 (86.2%)	122 (87.1%)	47 (92.2%)
Black or African American	9 (9.6%)	11 (7.9%)	2 (3.9%)
Asian	2 (2.1%)	1 (0.7%)	1 (2.0%)
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	2 (2.1%)	6 (4.3%)	1 (2.0%)
Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Weight (kg)			
n	94	139	51
Mean (Std Dev)	77.6 (17.5)	76.2 (16.6)	80.8 (20.5)
Median	77.3	77.0	77.3
Range	(44.4, 136.0)	(40.0, 136.4)	(53.1, 145.0)
Height (cm)			
n	94	139	51
Mean (Std Dev)	169.5 (11.3)	169.5 (10.1)	171.0 (10.6)
Median	170.0	170.0	170.0
Range	(140.0, 196.0)	(137.0, 193.0)	(150.0, 193.0)
Note: All percentages based on number of subjects enrolled.			

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Table 4. Subject Pre-Treatment Medical History

	TAG 99-01 Control	TAG 99-01	TAG 03-03
Subjects Enrolled	**94**	**140**	**51**
Coronary Artery Disease	34 (36.2%)	69 (49.3%)	18 (35.3%)
Cardiac Arrhythmia	29 (30.9%)	33 (23.6%)	16 (31.4%)
Valvular Heart Disease	9 (9.6%)	9 (6.4%)	5 (9.8%)
Congestive Heart Failure	9 (9.6%)	13 (9.3%)	4 (7.8%)
Stroke	9 (9.6%)	14 (10.0%)	4 (7.8%)
Peripheral Arterial Occlusive Disease	10 (10.6%)	22 (15.7%)	7 (13.7%)
Prior Vascular Intervention	52 (55.3%)	63 (45.0%)	29 (56.9%)
Thromboembolic Event	6 (6.4%)	10 (7.1%)	4 (7.8%)
Aneurysm Symptomatic	36 (38.3%)	30 (21.4%)	14 (27.5%)
Aneurysm of Traumatic Origin	5 (5.3%)	8 (5.7%)	2 (3.9%)
Other Concomitant Aneurysm(s)	26 (27.7%)	40 (28.6%)	17 (33.3%)
COPD	36 (38.3%)	56 (40.0%)	22 (43.1%)
History of Smoking	77 (81.9%)	117 (83.6%)	43 (84.3%)
Renal Dialysis	0 (0.0%)	2 (1.4%)	2 (3.9%)
Paraplegia	0 (0.0%)	1 (0.7%)	0 (0.0%)
Erectile Dysfunction	5 (10.4%)	13 (16.3%)	1 (3.0%)
Hepatic Dysfunction	1 (1.1%)	3 (2.1%)	2 (3.9%)
Bleeding Disorder(s)	5 (5.3%)	4 (2.9%)	2 (3.9%)
Cancer	12 (12.8%)	27 (19.3%)	16 (31.4%)
NYHA Classification			
I	22 (23.4%)	39 (27.9%)	21 (41.2%)
II	14 (14.9%)	35 (25.0%)	14 (27.5%)
III	12 (12.8%)	7 (5.0%)	3 (5.9%)
IV	0 (0.0%)	0 (0.0%)	0 (0.0%)
N/A	46 (48.9%)	59 (42.1%)	13 (25.5%)
ASA Classification			
I	2 (2.1%)	2 (1.4%)	3 (5.9%)
II	5 (5.3%)	13 (9.3%)	4 (7.8%)
III	51 (54.3%)	90 (64.3%)	31 (60.8%)
IV	36 (38.3%)	35 (25.0%)	13 (25.5%)
V	0 (0.0%)	0 (0.0%)	0 (0.0%)
Summary SVS Risk Score			
n	94	140	51
Mean (Std Dev)	4.84 (2.76)	5.36 (2.84)	5.88 (2.84)
Median	4.00	5.71	6.00
Range	(0.00, 13.00)	(0.00, 13.00)	(0.00, 11.00)
Note: All percentages based on number of subjects enrolled.			

Table 5 lists the initial aneurysm diameter sizes treated.

Table 5. Aneurysm Diameter Distribution

	TAG 99-01 Control	TAG 99-01	TAG 03-03
Subjects Enrolled	**94**	**140**	**51**
Diameter Range			
10-19 mm	0 (0.0%)	0 (0.0%)	0 (0.0%)
20-29 mm	1 (1.1%)	1 (0.7%)	0 (0.0%)
30-39 mm	3 (3.2%)	5 (3.6%)	0 (0.0%)
40-49 mm	5 (5.3%)	17 (12.1%)	5 (9.8%)
50-59 mm	17 (18.1%)	20 (14.3%)	14 (27.5%)
60-69 mm	30 (31.9%)	46 (32.9%)	23 (45.1%)
70-79 mm	16 (17.0%)	28 (20.0%)	7 (13.7%)
80-89 mm	8 (8.5%)	15 (10.7%)	1 (2.0%)
90-99 mm	2 (2.1%)	5 (3.6%)	1 (2.0%)
100-109 mm	1 (1.1%)	1 (0.7%)	0 (0.0%)
110-119 mm	2 (2.1%)	1 (0.7%)	0 (0.0%)
Missing	9 (9.6%)	1 (0.7%)	0 (0.0%)
Note: All percentages based on number of subjects enrolled.			

Outcomes

The primary and secondary objectives of TAG 99-01 and TAG 03-03 trials were met. Subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced a greater probability of remaining free from a MAE than subjects treated with open surgical repair. In addition, data from the TAG 99-01 and TAG 03-03 studies demonstrated that the GORE® TAG® Device subjects experienced a low incidence of major device-related events. Also, subjects treated with the endoprosthesis experienced less blood loss during the procedure, shorter ICU stay, shorter hospital stay and shorter time to return to normal daily activities than subjects treated with open surgical repair. The detailed results are separated into Safety, Effectiveness and Secondary Endpoints.

Table 6 lists the number of devices implanted for TAG 99-01 and TAG 03-03. More than 50% of subjects required more than one device (**Table 7**). Some subjects had more than one size device implanted.

Table 6. Devices Implanted

	TAG 99-01	TAG 03-03
Number of Devices	**234**	**94**
Endoprosthesis Diameter (mm)		
26	9 (3.8%)	2 (2.1%)
28	9 (3.8%)	6 (6.4%)
31	32 (13.7%)	11 (11.7%)
34	102 (43.6%)	29 (30.9%)
37	41 (17.5%)	26 (27.7%)
40	41 (17.5%)	20 (21.3%)
Note: All percentages based on number of devices implanted.		

Table 7. Number of Endoprostheses Implanted at Initial Procedure

	TAG 99-01	TAG 03-03
Number of Subjects	**140**	**51**
Number of Devices Implanted		
0	3 (2.1%)[1]	0 (0.0%)
1	61 (43.6%)	17 (33.3%)
2	60 (42.9%)	25 (49.0%)
3	11 (7.9%)	9 (17.6%)
4	5 (3.6%)	0 (0.0%)
[1] There were three patients with access failures who did not receive a device.		

Safety

Adverse events were characterized by severity, e.g., major or minor, as defined below:

Major

- Requires therapy, minor hospitalization (< 48 hours), or
- Major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), or
- Permanent adverse sequelae, or
- Death

Minor

- Requires no therapy, no consequence, or
- Nominal therapy, no consequence; includes overnight admission for observation only

The primary safety endpoint for the Pivotal Study (TAG 99-01), the proportion of subjects who experienced ≥ 1 MAE through one year post-treatment, was significantly lower ($p < 0.001$) in the TAG 99-01 GORE® TAG® Device group (42%) vs. the TAG 99-01 Open Surgical Control group (77%). Through 30 days post-treatment GORE® TAG® Device subjects experienced significantly fewer bleeding, pulmonary, renal, wound and neurological complications compared to Open Surgical Control subjects. This benefit was maintained throughout the five year follow-up period. Notably, among the clinically significant major complications, 4 / 140 (3%) in the TAG 99-01 GORE® TAG® Device group and 13 / 94 (14%) in the TAG 99-01 Open Surgical Control group experienced paraplegia or paraparesis. **Tables 8–11** and **Figures 3–5** describe the morbidity and mortality outcomes for TAG 99-01 and TAG 03-03. The GORE® TAG® Device subjects experienced significantly less major adverse events for both TAG 99-01 and TAG 03-03. Aneurysm-related mortality is also less in the GORE® TAG® Device group. All-cause mortality is not different between the GORE® TAG® Device and Open Surgical Control groups.

Figure 3. Subjects Free of a Major Adverse Event

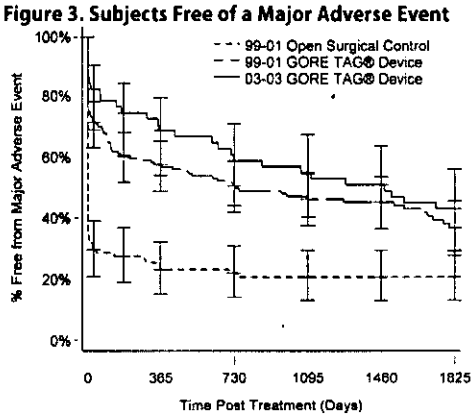

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Table 8. Subjects Free of a Major Adverse Event

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval [1]	N Censored During Interval [1]	Proportion Free from Major Adverse Event	95% C.I.[2]
TAG 99-01 Open Surgical Control					
0	94	51 (51)	0 (0)	0.457	(0.355, 0.554)
(0-30]	43	15 (66)	0 (0)	0.298	(0.209, 0.392)
(30-182]	28	2 (68)	1 (1)	0.276	(0.190, 0.369)
(182-365]	25	4 (72)	0 (1)	0.232	(0.152, 0.322)
(365-730]	21	1 (73)	2 (3)	0.220	(0.142, 0.309)
(730-1095]	18	1 (74)	2 (5)	0.208	(0.132, 0.296)
(1095-1460]	15	0 (74)	1 (6)	0.208	(0.132, 0.296)
(1460-1825]	14	0 (74)	14 (20)	0.208	(0.132, 0.296)
TAG 99-01 GORE® TAG® Device					
0	140	25 (25)	0 (0)	0.821	(0.747, 0.876)
(0-30]	115	15 (40)	2 (2)	0.714	(0.631, 0.781)
(30-182]	98	15 (55)	0 (2)	0.604	(0.518, 0.680)
(182-365]	83	4 (59)	1 (3)	0.575	(0.488, 0.652)
(365-730]	78	9 (68)	6 (9)	0.506	(0.419, 0.586)
(730-1095]	63	5 (73)	8 (17)	0.462	(0.375, 0.544)
(1095-1460]	50	1 (74)	4 (21)	0.453	(0.366, 0.535)
(1460-1825]	45	7 (81)	38 (59)	0.368	(0.279, 0.457)
TAG 03-03 GORE® TAG® Device					
0	51	6 (6)	0 (0)	0.882	(0.757, 0.945)
(0-30]	45	3 (9)	0 (0)	0.824	(0.688, 0.904)
(30-182]	42	4 (13)	0 (0)	0.745	(0.602, 0.843)
(182-365]	38	3 (16)	0 (0)	0.686	(0.540, 0.795)
(365-730]	35	5 (21)	0 (0)	0.588	(0.441, 0.709)
(730-1095]	30	2 (23)	0 (0)	0.549	(0.403, 0.673)
(1095-1460]	28	2 (25)	0 (0)	0.510	(0.366, 0.636)
(1460-1825]	26	4 (29)	22 (22)	0.430	(0.293, 0.560)

Pairwise Logrank p-values:
'99-01 GORE® TAG® Device' '99-01 Open Surgical Control' p=<.001
'03-03 GORE® TAG® Device' '99-01 Open Surgical Control' p=<.001

[1] Number in Parenthesis represents cumulative events or censored observations through end of interval

[2] At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

Table 9. Incidence of Major Adverse Events

	Post-Treatment Follow-up Period					
	0-30 Days	**31-365 Days**	**1-2 Years**	**2-3 Years**	**3-4 Years**	**4-5 Years**
TAG 99-01 Open Surgical Control						
Number of Subjects	94	88	72	60	42	33
Any Major Adverse Event	66 (70.2%)	19 (21.6%)	4 (5.6%)	3 (5.0%)	1 (2.4%)	1 (3.0%)
Bleeding Complication	50 (53.2%)	1 (1.1%)	-	-	-	-
Coagulopathy	9 (9.6%)	-	-	-	-	-
Hematoma	1 (1.1%)	1 (1.1%)	-	-	-	-
Post-Procedure Bleeding	13 (13.8%)	-	-	-	-	-
Procedural Bleeding	39 (41.5%)	-	-	-	-	-
Neurologic Complication	30 (31.9%)	4 (4.5%)	1 (1.4%)	-	-	-
Cerebrovascular Accident	4 (4.3%)	3 (3.4%)	1 (1.4%)	-	-	-
Change In Mental Status	16 (17.0%)	1 (1.1%)	-	-	-	-
Femoral Neuropathy	2 (2.1%)	-	-	-	-	-
Nerve Injury	3 (3.2%)	-	-	-	-	-
Paraplegia/Paraparesis	10 (10.6%)	-	-	-	-	-
Spinal Neurological Deficit	3 (3.2%)	-	-	-	-	-
Pulmonary Complication	31 (33.0%)	8 (9.1%)	-	2 (3.3%)	1 (2.4%)	-
Atelectasis/Pneumonia	17 (18.1%)	4 (4.5%)	-	1 (1.7%)	1 (2.4%)	-
Pulmonary Embolism	1 (1.1%)	1 (1.1%)	-	-	-	-
Respiratory Failure	19 (20.2%)	4 (4.5%)	-	1 (1.7%)	-	-
Renal Function Complication	12 (12.8%)	3 (3.4%)	-	-	-	-
Renal Failure	5 (5.3%)	2 (2.3%)	-	-	-	-
Renal Insufficiency	7 (7.4%)	2 (2.3%)	-	-	-	-
Vascular Complication	4 (4.3%)	2 (2.3%)	-	-	-	-
Embolism	1 (1.1%)	-	-	-	-	-
Restenosis	-	1 (1.1%)	-	-	-	-
Thrombosis	3 (3.2%)	1 (1.1%)	-	-	-	-
Cardiac Complication	19 (20.2%)	7 (8.0%)	2 (2.8%)	1 (1.7%)	-	1 (3.0%)
Arrhythmia	18 (19.1%)	3 (3.4%)	-	-	-	-
Congestive Heart Failure	2 (2.1%)	4 (4.5%)	-	1 (1.7%)	-	1 (3.0%)
Myocardial Infarction	1 (1.1%)	1 (1.1%)	2 (2.8%)	-	-	-
Wound Complication	11 (11.7%)	3 (3.4%)	1 (1.4%)	-	-	-
Dehiscence	3 (3.2%)	1 (1.1%)	-	-	-	-
Leg Edema	1 (1.1%)	-	-	-	-	-
Lymphocele/Lymph Fistula	1 (1.1%)	2 (2.3%)	1 (1.4%)	-	-	-
Wound Infection	10 (10.6%)	1 (1.1%)	-	-	-	-
Bowel Complication	6 (6.4%)	-	-	-	-	-
Adynamic Ileus	4 (4.3%)	-	-	-	-	-
Bowel Ischemia	2 (2.1%)	-	-	-	-	-
Bowel Obstruction	1 (1.1%)	-	-	-	-	-
Other Complication	1 (1.1%)	2 (2.3%)	-	-	-	-
Aortoenteric Fistula	-	1 (1.1%)	-	-	-	-
Prosthesis Infection	1 (1.1%)	1 (1.1%)	-	-	-	-
	Post-Treatment Follow-up Period					
	0-30 Days	**31-365 Days**	**1-2 Years**	**2-3 Years**	**3-4 Years**	**4-5 Years**
TAG 99-01 GORE® TAG® Device						
Number of Subjects	140	135	109	88	73	65
Any Major Adverse Event	40 (28.6%)	30 (22.2%)	13 (11.9%)	9 (10.2%)	5 (6.8%)	13 (20.0%)
Bleeding Complication	13 (9.3%)	3 (2.2%)	2 (1.8%)	-	-	-
Coagulopathy	-	1 (0.7%)	-	-	-	-
Hematoma	4 (2.9%)	2 (1.5%)	-	-	-	-
Post-Procedure Bleeding	4 (2.9%)	-	2 (1.8%)	-	-	-
Neurologic Complication	11 (7.9%)	4 (3.0%)	3 (2.8%)	1 (1.1%)	-	3 (4.6%)
Cerebrovascular Accident	5 (3.6%)	2 (1.5%)	1 (0.9%)	-	-	2 (3.1%)
Change In Mental Status	3 (2.1%)	2 (1.5%)	1 (0.9%)	-	-	-
Nerve Injury	1 (0.7%)	-	-	-	-	-
Paraplegia/Paraparesis	3 (2.1%)	-	-	-	-	-
Spinal Neurological Deficit	1 (0.7%)	-	1 (0.9%)	-	-	-

Transient Ischemic Attack	-	-	-	1 (1.1%)	-	1 (1.5%)
Pulmonary Complication	9 (6.4%)	13 (9.6%)	6 (5.5%)	2 (2.3%)	2 (2.7%)	5 (7.7%)
Atelectasis/Pneumonia	6 (4.3%)	11 (8.1%)	2 (1.8%)	2 (2.3%)	1 (1.4%)	3 (4.6%)
Pulmonary Embolism	-	-	1 (0.9%)	-	1 (1.4%)	1 (1.5%)
Respiratory Failure	6 (4.3%)	5 (3.7%)	4 (3.7%)	1 (1.1%)	-	2 (3.1%)
Renal Function Complication	2 (1.4%)	4 (3.0%)	1 (0.9%)	-	-	-
Renal Failure	1 (0.7%)	2 (1.5%)	1 (0.9%)	-	-	-
Renal Insufficiency	1 (0.7%)	2 (1.5%)	-	-	-	-
Vascular Complication	20 (14.3%)	5 (3.7%)	-	2 (2.3%)	2 (2.7%)	-
Embolism	3 (2.1%)	-	-	-	-	-
Pseudoaneurysm	-	2 (1.5%)	-	-	-	-
Thrombosis	6 (4.3%)	2 (1.5%)	-	1 (1.1%)	-	-
Vascular Trauma	14 (10.0%)	1 (0.7%)	-	1 (1.1%)	2 (2.7%)	-
Cardiac Complication	4 (2.9%)	18 (13.3%)	7 (6.4%)	5 (5.7%)	1 (1.4%)	4 (6.2%)
Angina	1 (0.7%)	-	-	1 (1.1%)	-	1 (1.5%)
Arrhythmia	3 (2.1%)	9 (6.7%)	6 (5.5%)	5 (5.7%)	-	-
Congestive Heart Failure	-	5 (3.7%)	2 (1.8%)	2 (2.3%)	-	2 (3.1%)
Myocardial Infarction	-	7 (5.2%)	1 (0.9%)	-	1 (1.4%)	1 (1.5%)
Wound Complication	8 (5.7%)	1 (0.7%)	1 (0.9%)	-	-	-
Dehiscence	3 (2.1%)	1 (0.7%)	1 (0.9%)	-	-	-
Lymphocele/Lymph Fistula	3 (2.1%)	-	-	-	-	-
Wound Infection	4 (2.9%)	1 (0.7%)	-	-	-	-
Bowel Complication	3 (2.1%)	3 (2.2%)	1 (0.9%)	-	1 (1.4%)	-
Adynamic Ileus	3 (2.1%)	1 (0.7%)	-	-	-	-
Bowel Ischemia	-	1 (0.7%)	-	-	-	-
Bowel Obstruction	-	1 (0.7%)	1 (0.9%)	-	1 (1.4%)	-
Other Complication	-	2 (1.5%)	-	-	-	-
Prosthesis Infection	-	2 (1.5%)	-	-	-	-
Additional Implantation	-	1 (0.7%)	1 (0.9%)	2 (2.3%)	-	1 (1.5%)
	Post-Treatment Follow-up Period					
	0-30 Days	**31-365 Days**	**1-2 Years**	**2-3 Years**	**3-4 Years**	**4-5 Years**
TAG 03-03 GORE® TAG® Device						
Number of Subjects	51	51	49	44	39	35
Any Major Adverse Event	8 (15.7%)	7 (13.7%)	7 (14.3%)	5 (11.4%)	3 (7.7%)	3 (8.6%)
Bleeding Complication	1 (2.0%)	1 (2.0%)	-	1 (2.3%)	-	-
Hematoma	1 (2.0%)	1 (2.0%)	-	1 (2.3%)	-	-
Neurologic Complication	2 (3.9%)	2 (3.9%)	1 (2.0%)	1 (2.3%)	1 (2.6%)	1 (2.9%)
Cerebrovascular Accident	2 (3.9%)	1 (2.0%)	-	-	-	1 (2.9%)
Change In Mental Status	-	2 (3.9%)	1 (2.0%)	1 (2.3%)	1 (2.6%)	-
Pulmonary Complication	3 (5.9%)	2 (3.9%)	2 (4.1%)	3 (6.8%)	2 (5.1%)	1 (2.9%)
Atelectasis/Pneumonia	3 (5.9%)	1 (2.0%)	1 (2.0%)	2 (4.5%)	2 (5.1%)	-
Respiratory Failure	-	2 (3.9%)	1 (2.0%)	1 (2.3%)	-	1 (2.9%)
Renal Function Complication	-	2 (3.9%)	-	1 (2.3%)	-	-
Renal Failure	-	1 (2.0%)	-	1 (2.3%)	-	-
Renal Insufficiency	-	1 (2.0%)	-	-	-	-
Vascular Complication	3 (5.9%)	-	2 (4.1%)	1 (2.3%)	-	-
Thrombosis	-	-	1 (2.0%)	1 (2.3%)	-	-
Vascular Trauma	3 (5.9%)	-	1 (2.0%)	-	-	-
Cardiac Complication	1 (2.0%)	1 (2.0%)	3 (6.1%)	1 (2.3%)	-	1 (2.9%)
Angina	1 (2.0%)	-	1 (2.0%)	-	-	-
Arrhythmia	-	-	1 (2.0%)	1 (2.3%)	-	1 (2.9%)
Congestive Heart Failure	-	1 (2.0%)	1 (2.0%)	-	-	-
Wound Complication	1 (2.0%)	1 (2.0%)	-	-	-	-
Wound Infection	1 (2.0%)	1 (2.0%)	-	-	-	-
Bowel Complication	-	-	-	-	1 (2.6%)	-
Bowel Ischemia	-	-	-	-	1 (2.6%)	-
Additional Implantation	-	1 (2.0%)	-	-	-	-

Note: Colum header counts and denominators are the number of subjects at risk at the start of each interval.
All visits through the 5 year visit are considered for analysis.

Figure 4. Aneurysm-Related Mortality

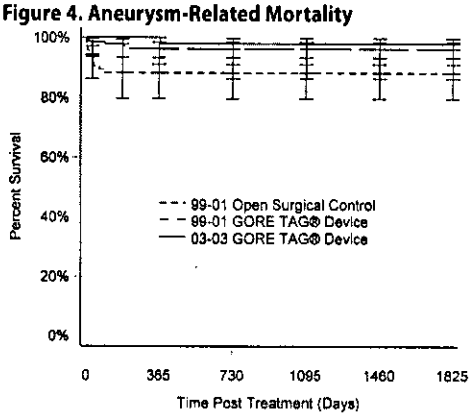

Table 10. Aneurysm-Related Mortality

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval [1]	N Censored During Interval [1]	Proportion Free from Events	95% C.I.[2]
TAG 99-01 Open Surgical Control					
0	94	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	94	6 (6)	0 (0)	0.936	(0.863, 0.971)
(30-182]	88	5 (11)	8 (8)	0.882	(0.797, 0.933)
(182-365]	75	0 (11)	3 (11)	0.882	(0.797, 0.933)
(365-730]	72	0 (11)	12 (23)	0.882	(0.797, 0.933)
(730-1095]	60	0 (11)	18 (41)	0.882	(0.797, 0.933)
(1095-1460]	42	0 (11)	9 (50)	0.882	(0.797, 0.933)
(1460-1825]	33	0 (11)	33 (83)	0.882	(0.797, 0.933)
TAG 99-01 GORE® TAG® Device					
0	140	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	140	2 (2)	3 (3)	0.985	(0.943, 0.996)
(30-182]	135	1 (3)	12 (15)	0.978	(0.933, 0.993)
(182-365]	122	2 (5)	11 (26)	0.962	(0.910, 0.984)
(365-730]	109	0 (5)	21 (47)	0.962	(0.910, 0.984)
(730-1095]	88	0 (5)	15 (62)	0.962	(0.910, 0.984)
(1095-1460]	73	0 (5)	7 (69)	0.962	(0.910, 0.984)
(1460-1825]	66	0 (5)	66 (135)	0.962	(0.910, 0.984)
TAG 03-03 GORE® TAG® Device					
0	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(30-182]	51	0 (0)	1 (1)	1.000	(1.000, 1.000)
(182-365]	50	0 (0)	1 (2)	1.000	(1.000, 1.000)
(365-730]	49	1 (1)	4 (6)	0.980	(0.864, 0.997)
(730-1095]	44	0 (1)	5 (11)	0.980	(0.864, 0.997)
(1095-1460]	39	0 (1)	4 (15)	0.980	(0.864, 0.997)
(1460-1825]	35	0 (1)	35 (50)	0.980	(0.864, 0.997)

Pairwise Logrank p-values:
'99-01 GORE® TAG® Device' '99-01 Open Surgical Control' p=0.015
'03-03 GORE® TAG® Device' '99-01 Open Surgical Control' p=0.040

[1] Number in Parenthesis represents cumulative events or censored observations through end of interval

[2] At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

Figure 5. All-Cause Mortality

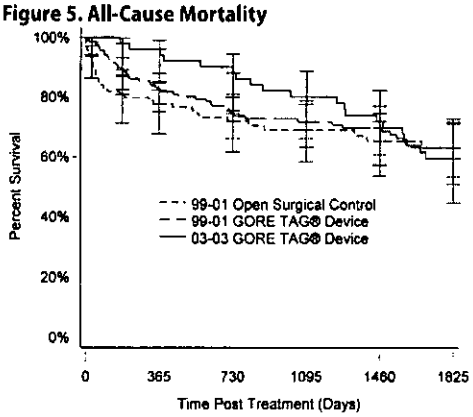

Table 11. All-Cause Mortality

Time Post Treatment (Days)	N at Risk at Start of Interval	N Events During Interval [1]	N Censored During Interval [1]	Proportion Free from Events	95% C.I.[2]
TAG 99-01 Open Surgical Control					
0	94	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	94	6 (6)	0 (0)	0.936	(0.863, 0.971)
(30-182]	88	12 (18)	1 (1)	0.808	(0.713, 0.875)
(182-365]	75	3 (21)	0 (1)	0.776	(0.677, 0.848)
(365-730]	72	5 (26)	7 (8)	0.720	(0.617, 0.800)
(730-1095]	60	2 (28)	16 (24)	0.690	(0.582, 0.776)
(1095-1460]	42	2 (30)	7 (31)	0.653	(0.538, 0.746)
(1460-1825]	33	1 (31)	32 (63)	0.630	(0.509, 0.728)
TAG 99-01 GORE® TAG® Device					
0	140	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	140	2 (2)	3 (3)	0.985	(0.943, 0.996)
(30-182]	135	13 (15)	0 (3)	0.891	(0.825, 0.932)
(182-365]	122	9 (24)	4 (7)	0.824	(0.749, 0.879)
(365-730]	109	10 (34)	11 (18)	0.745	(0.662, 0.811)
(730-1095]	88	3 (37)	12 (30)	0.718	(0.632, 0.787)
(1095-1460]	73	2 (39)	5 (35)	0.698	(0.609, 0.770)
(1460-1825]	66	6 (45)	60 (95)	0.630	(0.534, 0.712)
TAG 03-03 GORE® TAG® Device					
0	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-30]	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(30-182]	51	1 (1)	0 (0)	0.980	(0.869, 0.997)
(182-365]	50	1 (2)	0 (0)	0.961	(0.852, 0.990)
(365-730]	49	4 (6)	1 (1)	0.882	(0.755, 0.945)
(730-1095]	44	4 (10)	1 (2)	0.801	(0.662, 0.888)
(1095-1460]	39	4 (14)	0 (2)	0.719	(0.572, 0.823)
(1460-1825]	35	6 (20)	29 (31)	0.595	(0.445, 0.717)

Pairwise Logrank p-values:
'99-01 GORE® TAG® Device' '99-01 Open Surgical Control' p=0.625
'03-03 GORE® TAG® Device' '99-01 Open Surgical Control' p=0.590

[1] Number in parentheses represents cumulative events or censored observations through end of interval.

[2] At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

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Table 12 delineates the incidence of aneurysm enlargement, rupture, conversion and additional GORE® TAG® Device implantations by study. TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects experienced a low incidence of aneurysm rupture, conversion and additional implantation. TAG 03-03 GORE® TAG® Device subjects experienced lower aneurysm growth rate throughout all follow-up periods compared to TAG 99-01 GORE® TAG® Device subjects. TAG 03-03 GORE® TAG® Device subjects were treated with the modified GORE® TAG® Thoracic Endoprosthesis.

Table 12. Aneurysm Enlargement, Rupture, Conversion and Additional GORE® TAG® Device Implantations

	Post-Treatment Follow-up Period (Days)					
	0-30	**31-365**	**366-730**	**731-1096**	**1097-1462**	**1463-1828**
TAG 99-01						
Number of Subjects[1]	140	135	109	88	73	65
Number of Subjects With Imaging[2]	-	106	76	64	51	48
Aneurysm Enlargement (≥ 5mm)	-	10 (9.4%)	7 (9.2%)	11 (17.2%)	7 (13.7%)	12 (25.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Conversion	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Additional TAG Implantation	0 (0.0%)	1 (0.7%)	1 (0.9%)	2 (2.3%)	0 (0.0%)	1 (1.5%)
TAG 03-03						
Number of Subjects[1]	51	51	49	44	39	35
Number of Subjects With Imaging[2]	-	39	37	36	31	24
Aneurysm Enlargement (≥ 5mm)	-	1 (2.6%)	0 (0.0%)	2 (5.6%)	1 (3.2%)	1 (4.2%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Conversion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)
Additional TAG Implantation	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[1] Denominator for Aneurysm Rupture, Conversion, and Additional GORE® TAG® Device Implantation.

[2] Denominator for Aneurysm Enlargement; Includes Subjects with CT or X-RAY assessments at baseline and in the given time window.

Effectiveness

The primary effectiveness outcome of TAG 99-01 and TAG 03-03 was the proportion of subjects treated with the GORE® TAG® Thoracic Endoprosthesis free from a major device-related event as reported by the investigative sites. Effectiveness was determined by a pre-defined rate of success of 80% for TAG 99-01 and was presented descriptively for TAG 03-03. Since device-related events associated with endovascular therapy are different than those associated with open surgical repair, no meaningful effectiveness comparisons may be made between the GORE® TAG® Device groups and the Open Surgical Control group, therefore, Open Surgical Control group data is not represented in the effectiveness data tables.

An imaging core laboratory was used as part of TAG 99-01 and TAG 03-03 to provide an independent assessment of the imaging data collected during these studies. Computed tomography films (CTA / CT) and radiographs (X-Ray) for study subjects were sent from the investigative sites to the imaging core laboratory to assess aortic morphology, vascular characteristics, and device integrity. Categories for endoleak are not mutually exclusive and therefore numbers of specific endoleak types may add to more than the total patients with endoleak.

There have been 20 device fractures (14%) identified by Investigational Sites, the Core Lab or W. L. Gore & Associates, Inc., in 19 subjects in the TAG 99-01 clinical study through five years post-treatment. One TAG 99-01 GORE® TAG® Device subject received an additional GORE® TAG® Thoracic Endoprosthesis secondary to device fracture with concomitant proximal endoleak. Following identification of these device fractures, the GORE® TAG® Thoracic Endoprosthesis was modified to reduce the failure mode. The modified device was used in the TAG 03-03 clinical study. No device fractures have been identified in any of the TAG 03-03 GORE® TAG® Device subjects.

Tables 13 and 14 summarize the incidence of site reported and Core Lab observations of device-related events in the TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects by study period. The GORE® TAG® Thoracic Endoprosthesis demonstrated a low rate of device complications in both TAG 99-01 and TAG 03-03 clinical studies. Most major device-related events occurred during the first six months post-treatment. The definition of 'major' used for adverse events also applies to the device events used for the effectiveness endpoint.

Table 13. Subjects With Major Device-Related Events by Follow-Up Periods (Site Reported)

	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
TAG 99-01							
Number of Subjects[1]	140	134	117	102	76	69	53
Number of Subjects with Imaging[2]	136	113	106	86	66	61	49
Any Major Device Event	6 (4.3%)	2 (1.5%)	0 (0.0%)	3 (2.9%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
Endoleak[3]	3 (2.1%)	1 (0.7%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	2 (1.4%)	1 (0.7%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IA	2 (1.4%)	1 (0.7%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IB	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Enlargement	1 (0.7%)	2 (1.5%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)

	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
TAG 03-03							
Number of Subjects[1]	51	51	49	46	41	38	31
Number of Subjects with Imaging[2]	51	15	45	38	35	31	24
Any Major Device Event	2 (3.9%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	1 (2.4%)	0 (0.0%)	0 (0.0%)
Endoleak[3]	2 (3.9%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IA	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IB	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	1 (2.4%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Time frames for each interval are as follows: 1 Month(0-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] The number of subjects remaining in follow up at the beginning of the interval is used to calculate percentage of device events.

[2] Device events such as endoleak, migration, material failure, and aneurysm enlargement should be considered with respect to number of subjects with imaging follow-up.

[3] Endoleaks are only reported in the time interval in which the event was first observed.

Table 14. Subjects With Device-Related Events by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period						
	1 Month	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
TAG 99-01							
Number of Subjects	140	140	140	140	140	140	140
Number of Subjects With CT Scan[1]	109	104	97	73	47	42	24
Number of Subjects With Baseline and Post-Baseline CT Scans[2]	103	87	83	65	42	40	24
Number of Subjects With X-Ray[3]	119	80	80	64	42	37	26
Endoleak[4]	11 (10.1%)	8 (7.7%)	6 (6.2%)	5 (6.8%)	0 (0.0%)	2 (4.8%)	1 (4.2%)
Type I	1	1	0	0	-	1	0
Type IA	1	1	0	0	-	1	0
Type IB	0	0	0	0	-	0	0
Type II	1	1	1	1	-	0	0
Type III	0	0	0	0	-	0	0
Type IV	0	0	0	0	-	0	0
Indeterminate	9	6	5	5	-	1	0
Unknown	0	0	0	0	-	0	1
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)	0 (0.0%)
Fracture	0 (0.0%)	2 (2.5%)	6 (7.5%)	12 (18.8%)	6 (14.3%)	5 (13.5%)	3 (11.5%)
Change in Aneurysm Diameter							
Increase (≥ 5mm)	2 (1.9%)	3 (3.4%)	5 (6.0%)	10 (15.4%)	5 (11.9%)	5 (12.5%)	3 (12.5%)
No Change	101 (98.1%)	62 (71.3%)	57 (68.7%)	31 (47.7%)	16 (38.1%)	16 (40.0%)	12 (50.0%)
Decrease (≥ 5mm)	0 (0.0%)	22 (25.3%)	21 (25.3%)	24 (36.9%)	21 (50.0%)	19 (47.5%)	9 (37.5%)
Prosthesis Migration	0 (0.0%)	2 (1.9%)	0 (0.0%)	6 (8.2%)	3 (6.4%)	4 (9.5%)	0 (0.0%)
	Post-Treatment Follow-up Period						
	1 Month	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
TAG 03-03							
Number of Subjects	51	51	51	51	51	51	51
Number of Subjects With CT Scan[1]	50	13	45	33	32	19	17
Number of Subjects With Baseline and Post-Baseline CT Scans[2]	48	11	43	33	32	19	17
Number of Subjects With X-Ray[3]	51	12	42	34	25	24	13
Endoleak[4]	3 (6.0%)	4 (30.8%)	4 (8.9%)	1 (3.0%)	0 (0.0%)	1 (5.3%)	1 (5.9%)
Type I	0	2	1	0	-	0	1
Type IA	0	2	1	0	-	0	0
Type IB	0	0	0	0	-	0	1
Type II	1	0	0	0	-	0	0
Type III	0	0	0	0	-	0	0
Type IV	0	1	0	0	-	0	0
Indeterminate	2	1	3	1	-	1	0
Unknown	0	0	0	0	-	0	0
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Change in Aneurysm Diameter							
Increase (≥ 5mm)	1 (2.1%)	1 (9.1%)	0 (0.0%)	1 (3.0%)	1 (3.1%)	1 (5.3%)	1 (5.9%)
No Change	47 (97.9%)	8 (72.7%)	21 (48.8%)	8 (24.2%)	10 (31.3%)	2 (10.5%)	4 (23.5%)
Decrease (≥ 5mm)	0 (0.0%)	2 (18.2%)	22 (51.2%)	24 (72.7%)	21 (65.6%)	16 (84.2%)	12 (70.6%)
Prosthesis Migration	0 (0.0%)	0 (0.0%)	1 (2.2%)	2 (6.1%)	0 (0.0%)	0 (0.0%)	1 (5.9%)

Time frames for each interval are as follows: 1 Month(0-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] Denominator for Endoleak, Aneurysm Rupture, and Prosthesis Migration.

[2] Denominator for Aneurysm Diameter Change

[3] Denominator for Fracture.

[4] Endoleaks are reported in each time interval in which an event was observed.

Four (4) GORE® TAG® Device subjects in TAG 99-01 and TAG 03-03 required implantation of an additional GORE® TAG® Device(s) post-operatively. These four subjects were implanted with seven additional GORE® TAG® Device(s) as listed in **Table 15.**

Table 15. Reasons for Implantation of Additional Devices

Reason for Intervention	Number of Devices
Endoleak	4
Endoleak and Aneurysm Enlargement	2
Aortic Dilation[1]	1
TOTAL	**7 (4 total subjects)**

[1] Aortic dilatation distal to treated aneurysm.

Table 16 lists the minor device-related events for both the TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects. The majority of the minor device-related events occurred in the first 30 days.

Table 16. Subjects With Minor Device-Related Events by Follow-Up Periods (Site Reported)

	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
TAG 99-01							
Number of Subjects[1]	140	134	117	102	76	69	53
Number of Subjects with Imaging[2]	136	113	106	86	66	61	49
Any Minor Device Event	24 (17.1%)	2 (1.5%)	0 (0.0%)	6 (5.9%)	4 (5.3%)	3 (4.3%)	3 (5.7%)
Endoleak[3]	21 (15.0%)	1 (0.7%)	0 (0.0%)	2 (2.0%)	1 (1.3%)	2 (2.9%)	1 (1.9%)
Type I	13 (9.3%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (1.4%)	0 (0.0%)
Type IA	12 (8.6%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
Type IB	2 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)
Type II	3 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	1 (1.4%)	1 (1.9%)
Type III	3 (2.1%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	4 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	2 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.9%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	1 (0.7%)	0 (0.0%)	3 (2.9%)	1 (1.3%)	0 (0.0%)	1 (1.9%)
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	3 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	2 (2.9%)	0 (0.0%)

	Post-Treatment Follow-up Period						
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months
TAG 03-03							
Number of Subjects[1]	51	51	49	46	41	38	31
Number of Subjects with Imaging[2]	51	15	45	38	35	31	24
Any Minor Device Event	9 (17.6%)	3 (5.9%)	2 (4.1%)	1 (2.2%)	0 (0.0%)	3 (7.9%)	0 (0.0%)
Endoleak[3]	6 (11.8%)	3 (5.9%)	2 (4.1%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
Type I	5 (9.8%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IA	4 (7.8%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IB	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	1 (2.0%)	0 (0.0%)	2 (4.1%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Indeterminate	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Related Device Event	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Access Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deployment Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unplanned Branch Vessel Occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prosthesis Migration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)
Prosthesis Material Failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aneurysm Enlargement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Device Complication at Follow-Up	3 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Time frames for each interval are as follows: 1 Month(0-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] The number of subjects remaining in follow up at the beginning of the interval is used to calculate percentage of device events.

[2] Device events such as endoleak, migration, material failure, and aneurysm enlargement should be considered with respect to number of subjects with imaging follow-up.

[3] Endoleaks are only reported in the time interval in which the event was first observed.

Secondary Endpoints

Table 17 describes the peri-procedural secondary endpoints for TAG 99-01 and TAG 03-03 GORE® TAG® Device subjects as well as TAG 99-01 Open Surgical Control subjects. The GORE® TAG® Device groups had improved clinical benefit over the surgical control with respect to blood loss, length of ICU and hospital stay and the time to return to normal activities.

Table 17. Secondary Endpoints

	TAG 99-01 Control	TAG 99-01	TAG 03-03
Subjects Enrolled	**94**	**140**	**51**
Blood loss during procedure (mL)			
n	52	133	51
Mean (Std Dev)	2401.9 (2719.1)	472.1 (859.4)	222.4 (198.0)
Median	1850.0	250.0	200.0
Range	(0.0, 14000.0)	(0.0, 8000.0)	(0.0, 1000.0)
Length of ICU stay (days)			
n	91	72	35
Mean (Std Dev)	5.1 (7.2)	5.0 (19.9)	1.7 (1.3)
Median	3.0	1.2	1.2
Range	(0.8, 54.7)	(0.5, 167.3)	(0.2, 5.9)
Length of hospital stay (days)			
n	94	140	51
Mean (Std Dev)	14.1 (14.2)	6.4 (17.5)	3.9 (3.3)
Median	9.0	3.0	3.0
Range	(1.0, 87.0)	(1.0, 190.0)	(1.0, 20.0)
Time to return to normal daily activities (days)			
n	52	114	49
Mean (Std Dev)	153.4 (201.3)	60.5 (82.6)	48.7 (100.0)
Median	80.0	30.0	18.0
Range	(17.0, 930.0)	(1.0, 413.0)	(3.0, 420.0)

Conclusions: TAG 99-01 and TAG 03-03

Data from TAG 99-01 and TAG 03-03 studies provide a reasonable assurance of safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis for the treatment of aneurysms of the descending thoracic aorta. Subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced a greater probability of remaining free from MAEs than subjects treated with open surgical repair. In addition, data from the TAG 99-01 and TAG 03-03 studies suggest that GORE® TAG® Thoracic Endoprosthesis subjects experienced a low incidence of major device-related events. Also, subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced less blood loss during the procedure, shorter ICU stay, shorter hospital stay and shorter time to return to normal daily activities than subjects treated with open surgical repair.

Use of the GORE® TAG® Thoracic Endoprosthesis in Ruptured Aneurysms of the Descending Thoracic Aorta: TAG 04-01

TAG 04-01 Rupture Arm Summary

TAG 04-01 is a non-randomized multi-center clinical trial designed to evaluate the safety and effectiveness of the GORE® TAG® Thoracic Endoprosthesis in the treatment of complex aortic pathologies. The data presented herein describe outcomes from a subset of 20 subjects treated for ruptured aneurysms of the DTA as part of this study. This cohort of subjects was enrolled at nine sites. Subjects were assessed at pre-treatment, treatment, and hospital discharge. Follow-up visits were scheduled at 1 month, 6 months, and annually thereafter through five years post-treatment. Subject disposition and compliance are presented in **Table 18**.

Data collected for these subjects included: subject characteristics, aneurysm diameter, device use, mortality, motor function evaluation, and adverse events (AEs). For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit). Enrollment for TAG 04-01 began in August 2005 and was completed in February 2007. Annual follow-up through five years post-treatment is ongoing.

Table 18. Subject Disposition and Compliance by Study Period

		Follow-Up Compliance				Events Prior to Next Interval		
Study Period	Eligible for Follow-Up[1]	Subjects with Visit in Window	CT Scan Performed[2,3]	X-Ray Performed[2,3]	Baseline[4] and Post-Baseline Aneurysm Max Diameter Measurement Available[5]	Death[2]	Discontinued[2]	Not Due for Next Follow-Up[2]
Treatment	20	20 (100.0%)	17 (85.0%)	19 (95.0%)	—	3 (15.0%)	0 (0.0%)	0 (0.0%)
1 Month	17	17 (100.0%)	16 (94.1%)	16 (94.1%)	—	0 (0.0%)	2 (11.8%)	0 (0.0%)
6 Months	15	12 (80.0%)	11 (73.3%)	10 (66.7%)	9 (81.8%)	7 (46.7%)	1 (6.7%)	0 (0.0%)
12 Months	7	5 (71.4%)	5 (71.4%)	5 (71.4%)	4 (80.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)
24 Months	5	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (100.0%)	0 (0.0%)	1 (20.0%)	3 (60.0%)
36 Months	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0	0 (0.0%)	0 (0.0%)	1 (100.0%)
48 Months	0	0	0	0	0	0	0	0
60 Months								

Study period definitions: Treatment (0-22 days), 1 Month (23-60 days), 6 Months (61-304 days), 12 Months (305-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days)

[1] Subjects are considered eligible for follow-up if time on the study is on or after the first day of the given time window and they have not discontinued or died prior to the start of the interval.

[2] Percentages for each entry are based on number of subjects eligible for follow-up. Compliance is based on site reported imaging assessments.

[3] Refer to individual results tables for the number of subjects with adequate imaging to assess the parameters provided in that specific results table.

[4] Baseline is defined as the imaging assessment closest to 30 days post treatment between day 15 and day 60.

[5] Denominator is number of subjects in visit window with CT scan performed.

Subject Characteristics

Tables 19 –20 show the demographics and pre-treatment medical history for the subset of TAG 04-01 subjects treated for ruptured aneurysms.

Table 19. Subject Demographics

Subjects Enrolled	**20**
Gender	
Male	14 (70.0%)
Female	6 (30.0%)
Race	
Black or African American	3 (15.0%)
White or Caucasian	17 (85.0%)
Age (yrs)	
n	20
Mean (Std Dev)	76.2 (10.7)
Median	79.8
Range	(50.6, 88.9)
Height (cm)	
n	20
Mean (Std Dev)	170.5 (14.0)
Median	172.5
Range	(140.0, 193.0)
Weight (kg)	
n	20
Mean (Std Dev)	79.6 (27.0)
Median	68.3
Range	(51.0, 159.0)
Note: All percentages based on number of subjects enrolled.	

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Table 20. Subject Pre-Treatment Medical History

Subjects Enrolled	20
Risk Factors	
Coronary Artery Disease	7 (35.0%)
Coronary Artery Bypass Graft	1 (5.0%)
Hypercholesterolemia	9 (45.0%)
Chronic Obstructive Pulmonary Disease	6 (30.0%)
Congestive Heart Failure	2 (10.0%)
Hypertension	18 (90.0%)
Cigarette Smoking	13 (65.0%)
Renal Insufficiency	3 (15.0%)
Stroke	2 (10.0%)
Diabetes Mellitus	5 (25.0%)
Peripheral Vascular Disease	5 (25.0%)
Thoracotomy	4 (20.0%)
Signs and Symptoms	
Back Pain	9 (45.0%)
Chest Pain	10 (50.0%)
Abdominal Pain	5 (25.0%)
Hypotension	1 (5.0%)
Dysphagia	2 (10.0%)
Hemoptysis	4 (20.0%)
Dysphonia	0 (0.0%)
NYHA Classification	
I	5 (25.0%)
II	8 (40.0%)
III	1 (5.0%)
IV	0 (0.0%)
No Cardiac Disease	4 (20.0%)
NA	2 (10.0%)
ASA Anesthetic Classification	
I	0 (0.0%)
II	3 (15.0%)
III	8 (40.0%)
IV	9 (45.0%)
V	0 (0.0%)
NA	0 (0.0%)
Summary SVS Risk Score	
n	20
Mean (Std Dev)	7.6 (5.6)
Median	6.3
Range	(1.0, 24.0)
Note: All percentages based on number of subjects enrolled.	

Table 21 shows a summary of the aneurysm diameters treated as part of the ruptured aneurysm cohort for the TAG 04-01 study.

Table 21. Aneurysm Diameter Measurements

Subjects Enrolled	20
Aortic Diameter (mm) Primary Lesion Maximum Outer Diameter	
n	20
Mean (Std Dev)	54.9 (22.1)
Median	59.5
Range	(10.0, 110.0)

Outcomes

Table 22 lists the number of devices implanted for the ruptured aneurysm subjects treated as part of the TAG 04-01 study. At initial procedure 50% of the subjects were treated with one device; 15% of the subjects required more than two devices.

Table 22. Devices Implanted

Number of Subjects with Successful Implant	20
Number of Implanted Endoprostheses (Total = Initial + Additional Implantation)[1]	
1	8 (40.0%)
2	8 (40.0%)
3	4 (20.0%)
4	0 (0.0%)
n	20
Mean (Std Dev)	1.8 (0.8)
Median	2.0
Range	(1.0, 3.0)

[1] Three patients had one additional device implanted.

Table 23 shows the treatment outcomes for the subset of subjects treated for ruptured aneurysms of the DTA as part of the TAG 04-01 study.

Table 23. Treatment Outcomes

Subjects Enrolled	20
Endoprosthesis Access Method	
Percutaneous	3 (15.0%)
Cutdown	17 (85.0%)
Procedure Time (min)	
n	20
Mean (Std Dev)	133.0 (67.5)
Median	101.5
Range	(55.0, 300.0)
Anesthesia Time (min)	
n	20
Mean (Std Dev)	237.8 (92.7)
Median	193.5
Range	(132.0, 488.0)
Endoprosthesis Access Outcome	
Success (Implanted)	20 (100.0%)
Failure (Discontinued)	0 (0.0%)

Estimated Blood Loss (ml)	
n	20
Mean (Std Dev)	368.8 (507.4)
Median	200.0
Range	(50.0, 2000.0)
Hospital Stay (Days)	
n	20
Mean (Std Dev)	7.2 (5.1)
Median	6.5
Range	(1.0, 21.0)
Subjects with ICU Stay	18 (90.0%)
ICU Stay (Days)	
n	18
Mean (Std Dev)	3.9 (3.9)
Median	2.2
Range	(0.4, 13.7)

Note: All percentages based on number of subjects enrolled.

Mortality

Table 24 shows subject deaths for the subset of subjects treated for ruptured aneurysms of the DTA as part of the TAG 04-01 Study. No subjects died intra-operatively. Through 30 days post-treatment there were three deaths, causes of death included: pre-existing osteomyelitis, myocardial infarction and cerebrovascular accident. Survival through 30 days post-treatment was 85%. The Kaplan-Meier survival estimate through one year post-treatment, which accounts for missing follow-up, was 37.4%.

Table 24. Subject Deaths

Days to Death	Cause of Death
1	Myocardial infarction
2	CVA, ischemic gut due to showering emboli
14	Osteomyelitis[1]
61	Subdural hematoma from a fall
101	Infected endograft[2]
106	Intracranial bleed
121	Cardiac arrest
164	Cardiac arrest
242	Pulmonary edema, cardiomyopathy
296	Pulmonary tuberculosis / pneumonia
360	Renal failure

[1] Subject initially presented with osteomyelitis. Aortic fistula suspected, but not confirmed, at treatment.

[2] Subject diagnosed with sepsis and endograft infection concomitantly. Cause of endograft infection was indeterminate.

Motor Function Evaluation

Subjects were assessed to determine the presence of paraplegia or paraparesis. No subject experienced paraplegia at any time. One subject experienced lower extremity weakness and left leg paraparesis during the one month follow-up period. This subject recovered without treatment from both incidences. No subject experienced paraparesis after the 30 day follow-up visit.

Adverse Events

All AEs were classified as major or minor based upon outcome and treatment required. A summary of the number of subjects that experienced ≥1 AE through one year is shown in **Table 25**. Most subjects that experienced a major or a device AE did so within five days of treatment. Only three subjects required re-intervention with a GORE® TAG® Device (**Table 26**); all of these were to treat endoleaks and occurred within seven days of the initial procedure.

Table 25. Summary of All Adverse Events Through One Year Follow-up Visit

	Major			Minor			All		
	1 Month	6 Months	12 Months	1 Month	6 Months	12 Months	1 Month	6 Months	12 Months
Evaluable Subjects[1]	20	15	7	20	15	7	20	15	7
Subjects with Imaging Assessment	19	12	5	19	12	5	19	12	5
Subjects with One or More Adverse Events	16 (80.0%)	9 (60.0%)	1 (14.3%)	11 (55.0%)	2 (13.3%)	—	18 (90.0%)	9 (60.0%)	1 (14.3%)
Subjects with One or More Implant-Related Adverse Events	5 (25.0%)	1 (6.7%)	—	6 (30.0%)	—	—	10 (50.0%)	1 (6.7%)	—
Endograft Infection	1 (5.0%)	1 (6.7%)	—	—	—	—	1 (5.0%)	1 (6.7%)	—
Access Failure	—	—	—	1 (5.0%)	—	—	1 (5.0%)	—	—
Endoleak[2]	3 (15.0%)	—	—	6 (30.0%)	—	—	8 (40.0%)	—	—
Other Implant Related Complication	2 (10.0%)	—	—	—	—	—	2 (10.0%)	—	—
Subjects with One or More Deployment—Related Adverse Events	4 (20.0%)	—	—	—	1 (6.7%)	—	4 (20.0%)	1 (6.7%)	—
Operative Bleeding	2 (10.0%)	—	—	—	—	—	2 (10.0%)	—	—
Arterial Perforation or Rupture	3 (15.0%)	—	—	—	—	—	3 (15.0%)	—	—
Access Site Lymphocele, Lymphorrhea, Lymphedema	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Fever of Unknown Origin	—	—	—	—	1 (6.7%)	—	—	1 (6.7%)	—
Subjects with One or More Systemic Adverse Events	14 (70.0%)	9 (60.0%)	1 (14.3%)	8 (40.0%)	1 (6.7%)	—	16 (80.0%)	9 (60.0%)	1 (14.3%)
Cardiac	4 (20.0%)	4 (26.7%)	1 (14.3%)	5 (25.0%)	—	—	8 (40.0%)	4 (26.7%)	1 (14.3%)
Pulmonary	7 (35.0%)	3 (20.0%)	—	7 (35.0%)	1 (6.7%)	—	13 (65.0%)	3 (20.0%)	—
Renal Insufficiency	1 (5.0%)	—	—	1 (5.0%)	—	—	2 (10.0%)	—	—
Cerebrovascular	1 (5.0%)	2 (13.3%)	—	—	—	—	1 (5.0%)	2 (13.3%)	—
Coagulopathy	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Bowel Ischemia	1 (5.0%)	—	—	—	—	—	1 (5.0%)	—	—
Spinal Cord Ischemia	—	—	—	1 (5.0%)	—	—	1 (5.0%)	—	—
Other Systemic Complication	6 (30.0%)	3 (20.0%)	1 (14.3%)	—	—	—	6 (30.0%)	3 (20.0%)	1 (14.3%)

[1] Subjects are considered evaluable if date of last contact for the subject is on or after the first day of the given time window. The percentages for each entry are based on the number of evaluable subjects in that time window.

[2] Endoleaks are only reported in the time interval in which the event was first observed.

Note 1: An event with a '—' indicates no subjects reported the event.

Note 2: Device events such as endoleak should be considered with respect to number of subjects with imaging follow-up.

Note 3: Study period definitions: 1 Month (0 - 60 days), 6 Months (61 - 304 days), 12 Months (305 - 546 days). Events with onset date prior to study day 0 are recoded to study day 0 for analysis.

Table 26. Revisions

Days to Revision	Revision	Reason for Revision
2	Reintervention (Additional GORE® TAG® Device)	Other implant related complication: intramural hematoma[1]
3	Additional GORE® TAG® Device deployed, coil embolization of left subclavian artery	Endoleak
7	Reintervention (Additional GORE® TAG® Device)	Endoleak
29	Explant	Other implant related complication: aorto-esophageal fistula
98	Embolization	Endoleak

[1] Intramural hematoma led to Type IA endoleak and subsequent revision

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Use of the 45mm GORE® TAG® Thoracic Endoprosthesis in the Descending Thoracic Aorta: TAG 06-02

TAG 06-02 45 mm GORE® TAG® Device Study and Emergency and Compassionate Use Summary

The 45 mm GORE® TAG® Device Study (TAG 06-02) is a non-randomized, multi-center study designed to assess the safety and efficacy of the 45 mm GORE® TAG® Device when used for the primary treatment of aneurysms of the DTA. Patient enrollment for TAG 06-02 began in February 2007, enrolling 21 subjects. In addition, 13 subjects were treated with the 45 mm GORE® TAG® Device under the provisions of Emergency and Compassionate (E&C) use for pathologies that were not part of the study protocol (**Table 27**), including rupture, elephant trunk procedures, debranching procedures, and treatment of aneurysms in which landing zones were outside of the recommended sizing guidelines. The data presented herein describe outcomes from both the 21 study subjects and the 13 patients treated with a 45 mm GORE® TAG® Device under the provisions of E&C use.

Table 27. Emergency and Compassionate Use Indications

	E&C Use Patients
Subjects Enrolled	**13**
E&C Use	
Rupture	5 (38.5%)
Elephant Trunk Procedure	3 (23.1%)
Debranching Procedure	3 (23.1%)
Landing Zone	2 (15.4%)
Note: All percentages based on number of subjects enrolled.	

Tables 28 – 29 show the demographics and pre-treatment medical history for the TAG 06-02 study subjects and E&C patients.

Table 28. Subject Demographics

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	**21**	**13**
Gender		
Male	18 (85.7%)	6 (46.2%)
Female	3 (14.3%)	7 (53.8%)
Ethnicity		
Hispanic or Latino	0 (0.0%)	0 (0.0%)
Not Hispanic or Latino	21 (100.0%)	13 (100.0%)
Race		
White or Caucasian	20 (95.2%)	12 (92.3%)
Black or African American	1 (4.8%)	1 (7.7%)
Asian	0 (0.0%)	0 (0.0%)
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)
Unknown	0 (0.0%)	0 (0.0%)
Age (yrs)		
n	21	13
Mean (Std Dev)	78.2 (6.2)	77.7 (4.0)
Median	78.9	79.1
Range	(60.1, 87.1)	(69.6, 83.3)
Weight (kg)		
n	21	13
Mean (Std Dev)	85.0 (12.6)	75.5 (14.3)
Median	88.4	75.0
Range	(60.2, 110.0)	(50.0, 99.0)
Height (cm)		
n	21	13
Mean (Std Dev)	174.0 (9.0)	169.1 (9.3)
Median	175.0	165.0
Range	(157.0, 187.0)	(157.0, 185.0)
Note: All percentages based on number of subjects enrolled.		

Table 29. Subject Pre-Treatment Medical History

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	**21**	**13**
Risk Factors		
Coronary Artery Disease	14 (66.7%)	9 (69.2%)
Cardiac Arrhythmia	8 (38.1%)	7 (53.8%)
Valvular Heart Disease	5 (23.8%)	5 (38.5%)
Congestive Heart Failure	2 (9.5%)	3 (23.1%)
Stroke	2 (9.5%)	0 (0.0%)
Peripheral Arterial Occlusive Disease	3 (14.3%)	3 (23.1%)
Prior Vascular Intervention	16 (76.2%)	8 (61.5%)
Thromboembolic Event	0 (0.0%)	0 (0.0%)
Aneurysm Symptomatic	5 (23.8%)	7 (53.8%)
Aneurysm of Traumatic Origin	0 (0.0%)	0 (0.0%)
Other Concomitant Aneurysm(s)	7 (33.3%)	7 (53.8%)
COPD	10 (47.6%)	5 (38.5%)
History of Smoking	19 (90.5%)	11 (84.6%)
Renal Dialysis	0 (0.0%)	1 (7.7%)
Paraplegia	0 (0.0%)	0 (0.0%)
Erectile Dysfunction	2 (11.1%)	0 (0.0%)
Cancer	9 (42.9%)	5 (38.5%)
NYHA Classification		
I	12 (57.1%)	4 (30.8%)
II	8 (38.1%)	5 (38.5%)
III	1 (4.8%)	2 (15.4%)
IV	0 (0.0%)	0 (0.0%)
No Cardiac Disease	0 (0.0%)	0 (0.0%)
N/A	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	2 (15.4%)
ASA Anesthetic Classification		
I	1 (4.8%)	0 (0.0%)
II	5 (23.8%)	2 (15.4%)
III	13 (61.9%)	6 (46.2%)
IV	2 (9.5%)	3 (23.1%)
V	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	2 (15.4%)
Summary SVS Risk Score		
n	21	13
Mean (Std Dev)	7.39 (2.10)	6.54 (2.33)
Median	7.00	7.00
Range	(3.00, 11.00)	(3.00, 10.00)
Note: All percentages based on number of subjects enrolled.		

Table 30 shows a summary of the aneurysm diameters treated as part of the TAG 06-02 study and E&C Use.

Table 30. Aneurysm Diameter Measurements

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	**21**	**13**
Primary Lesion Maximum Outer Diameter		
n	21	11[1]
Mean (Std Dev)	64.5(8.3)	72.5(8.6)
Median	63.0	70.0
Range	(46.0, 86.0)	(62.7, 90.0)
[1] Data is unavailable for two E&C use patients treated for rupture.		

Outcomes

Table 31 lists the number of devices implanted for the TAG 06-02 study subjects and E&C patients. Two subjects (one study subject and one E&C patient) required additional implantations.

Table 31. Devices Implanted

	TAG 06-02 Study Subjects	E&C Use Patients
Number of Subjects with Successful Initial Implant	**21** (100%)	**13** (100%)
Number of Implanted Devices (Total = Initial + Additional Implantation)[1]		
1	3 (14.3%)	2 (15.4%)
2	9 (42.9%)	2 (15.4%)
3	8 (38.1%)	7 (53.8%)
4	1 (4.8%)	0 (0.0%)
5	0 (0.0%)	1 (7.7%)
6	0 (0.0%)	1 (7.7%)
n	21	13
Mean (Std Dev)	2.3(0.8)	2.9(1.4)
Median	2.0	3.0
Range	(1.0, 4.0)	(1.0, 6.0)

[1] One TAG 06-02 study subject had an additional device implant at two days post-treatment; one E&C use patient had additional device implants at four months post-treatment.

Table 32 shows the treatment outcomes for the TAG 06-02 study subjects and E&C patients.

Table 32. Treatment Outcomes

	TAG 06-02 Study Subjects	E&C Use Patients
Subjects Enrolled	**21**	**13**
Conduit Use		
Yes	4 (19.0%)	2 (15.4%)
No	17 (81.0%)	8 (61.5%)
Missing	0 (0.0%)	3 (23.1%)
Procedure Time (min)		
n	20	13
Mean (Std Dev)	136.1(74.38)	206.1(85.19)
Median	107.0	192.0
Range	(73.0, 362.0)	(98.0, 373.0)
Estimated Blood Loss (ml)		
n	21	12[1]
Mean (Std Dev)	328.6(383.92)	344.2(542.13)
Median	150.0	162.5
Range	(50.0, 1600.0)	(5.0, 2000.0)

[1] Data is unavailable for one E&C use patient.

Mortality

Table 33 shows subject deaths for the TAG 06-02 study subjects and E&C patients. No subject died intra-operatively. Through 30 days post-treatment there was one death in a study subject and two deaths in E&C patients.

Table 33. Subject Deaths

Cohort	Days to Death	Cause of Death
45 mm GORE® TAG® Device	11	Hematoma[1]
45 mm GORE® TAG® Device	51	Atelectasis / Pneumonia
45 mm GORE® TAG® Device	167	Sepsis
45 mm E&C	3	Sepsis
45 mm E&C	10	Other Multi-organ system failure
45 mm E&C	39	Respiratory Failure

[1] Subject developed epidural hematoma secondary to spinal drain.

Adverse Events

Major adverse events reported through one month are summarized in **Table 34**, with data from TAG 03-03 and TAG 99-01 provided for reference. Study subjects experienced bleeding, neurologic, pulmonary, vascular, and wound complications. Emergency & Compassionate use patients experienced pulmonary, vascular, cardiac, and wound complications. Of note, three study subjects experienced neurologic complications. One subject experienced paraplegia of both lower extremities one day post-treatment; a cerebrovascular accident (CVA) was confirmed three days post-treatment. This subject expired eleven days post-treatment (**Table 33**). Two additional subjects reported CVAs the day of treatment; one subject recovered within four days of initial onset and another subject reported the event as continuing. No neurologic complications were reported for E&C use patients.

No unanticipated adverse device events were reported. One major device event was reported for a study subject requiring an additional implantation of a GORE® TAG® Device for a type III endoleak two days post-treatment. One E&C use patient experienced a major device event through 30 days post-treatment, a type I endoleak on the day of treatment requiring embolization.
Available longer term follow-up includes one reported death in a TAG 06-02 study subject due to sepsis (**Table 33**) 167 days post-treatment and three additional GORE® TAG® Device implants in one E&C use patient to repair a type III endoleak four months post-procedure with concomitant hematoma, renal failure, respiratory failure and atelectasis / pneumonia. Complete ascertainment of long-term follow-up for TAG 06-02 study subjects is ongoing.
No aneurysm ruptures or surgical conversions were reported in study subjects or E&C use patients.

Table 34. Short Term Major Adverse Events

	TAG 99-01 (N=140)	TAG 03-03 (N=51)	TAG 06-02 (N=21)	TAG 06-02 E&C (N=13)
Bleeding Complication	13 (9.3%)	1 (2.0%)	4 (19.0%)	0
Neurologic Complication	11 (7.9%)	2 (3.9%)	3 (14.3%)	0
Pulmonary Complication	9 (6.4%)	3 (5.9%)	2 (9.5%)	3 (23.1%)
Renal Function Complication	2 (1.4%)	0	0	0
Vascular Complication	20 (14.3%)	3 (5.9%)	1 (4.8%)	2 (15.4%)
Cardiac Complication	4 (2.9%)	1 (2.0%)	0	2 (15.4%)
Wound Complication	8 (5.7%)	1 (2.0%)	2 (9.5%)	1 (7.7%)
Bowel Complication	3 (2.1%)	0	0	0
Other Complication	0	0	0	0
Major Device Event[1]	6 (4.3%)	2 (3.9%)	1 (4.8%)	1 (7.7%)
Additional Implantation[1]	0	0	1 (4.8%)	0
[1] Data presented through one month time window (0-59 days)				

Use of the GORE® TAG® Thoracic Endoprosthesis in Aneurysms of the Descending Thoracic Aorta: TAG 08-03

TAG 08-03 Summary

After commercialization of the GORE® TAG® Thoracic Endoprosthesis (TAG 03-03 design), device compressions were identified in a number of patients when the device was used outside of the indications for use and / or sizing guidelines. Device compression may result in partial or full occlusion of the vessel, endoleak, reintervention, surgical conversion, or death. Modifications were made to the device to increase the compression resistance and increase the conformability of the device. TAG 08-03 was designed to confirm that the modifications did not adversely affect the peri-operative (through 30 days) performance of the device.
TAG 08-03 was a non-randomized, multi-center clinical study designed to evaluate the modified GORE® TAG® Thoracic Endoprosthesis for the treatment of aneurysms of the DTA. Fifty-one (51) subjects were enrolled at 20 investigative sites. Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1 month with additional visits at 6, 12, 24, 36, 48, and 60 months post-treatment. Subject disposition and compliance is presented in **Table 35.**
An imaging core laboratory provided an independent assessment of the imaging data collected during this study. Site evaluation is also presented in this summary because the study hypotheses required an evaluation of the clinical significance of adverse events (i.e., major vs minor). Clinical events were adjudicated by a clinical events committee, and safety was monitored by a data safety monitoring board. Data lock for the site reported and core laboratory data presented in this summary was 5 January 2011.
The primary endpoint of the study was the proportion of subjects who experienced a major device-related event (MDE) through 1 month in comparison to a pre-defined rate of success (> 83% freedom from MDE). At least 44 subjects were required to test this hypothesis for 80% power. An MDE is defined as any of the following events that require major therapy, unplanned increase in level of care, and/or prolonged hospitalization > 48 hours; results in permanent adverse sequelae; or results in death.

- Access failure
- Branch vessel occlusion
- Deployment failure
- Endoleak
- Prosthesis migration
- Prosthesis material failure
- Extrusion/erosion
- Lumen obstruction
- Aneurysm rupture
- Aneurysm enlargement

Secondary objectives included an assessment of clinical benefits and quality-of-life measures. Enrollment began in October 2009 and was completed in October 2010. Annual follow-up through five years post-treatment is ongoing.

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Table 35 provides the disposition and compliance for subjects enrolled into the TAG 08-03 clinical study. Available subjects are defined as those that are alive and participating in the study for that follow-up period. For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit).

Table 35. Subject Disposition and Compliance by Study Period

		Follow-up Compliance			Events Prior to Next Interval		
Study Period	Eligible for follow-up[1]	Subjects with Visit in Window	CT Scan performed[2,3]	X-Ray performed[2,3]	Death[1]	Discontinued[2]	Not Due for Next F/U[2]
Procedure	51	-	-	-	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Procedure	51	-	-	-	1 (2.0%)	1 (2.0%)	0 (0.0%)
1 Month	49	47 (95.9%)	45 (91.8%)	45 (91.8%)	1 (2.0%)	0 (0.0%)	0 (0.0%)
6 Months	48	27 (56.3%)	27 (56.3%)	26 (54.2%)	3 (6.3%)	1 (2.1%)	28 (58.3%)
12 Months	16	3 (18.8%)	3 (18.8%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	16 (100.0%)
24 Months	0	-	-	-	-	-	-
36 Months	0	-	-	-	-	-	-
48 Months	0	-	-	-	-	-	-
60 Months	0	-	-	-	-	-	-

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] Subjects are considered eligible for follow-up if time on the study is on or after the first day of the given time window and they have not discontinued or died prior to the start of the interval.

[2] Percentages are based on number of subjects in visit window. Compliance is based on site reported imaging assessments.

[3] Refer to individual results tables for the number of subjects with adequate imaging to assess the parameters provided in that specific results table.

Subject Characteristics

Tables 36 - 37 list TAG 08-03 subject demographics and pre-treatment medical history.

Table 36. Subject Demographics

	TAG 08-03
Number of Enrolled Subjects	**51**
Gender	
Male	34 (66.7%)
Female	17 (33.3%)
Ethnicity	
Not Hispanic or Latino	50 (98.0%)
Hispanic or Latino	1 (2.0%)
Race	
White or Caucasian	44 (86.3%)
Black or African American	5 (9.8%)
Asian / Oriental	1 (2.0%)
American Indian or Alaskan Native	0 (0.0%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)
Middle Eastern	0 (0.0%)
Other	1 (2.0%)
Unknown	0 (0.0%)
Age (yrs)	
n	51
Mean (Std Dev)	71.9 (9.8)
Median	72.0
Range	(45.0, 87.0)
Weight (kg)	
n	51
Mean (Std Dev)	82.7 (22.4)
Median	80.0
Range	(38.1, 189.6)
Height (cm)	
n	51
Mean (Std Dev)	171.5 (9.4)
Median	172.2
Range	(152.0, 188.0)
Note: All percentages based on number of subjects enrolled.	

Table 37. Subject Pre-Treatment Medical History

	TAG 08-03
Number of Enrolled Subjects	**51**
Hypertension	50 (98.0%)
Cigarette Smoking	39 (76.5%)
Hypercholesterolemia	39 (76.5%)
Prior Vascular Intervention	27 (52.9%)
CAD	24 (47.1%)
COPD	24 (47.1%)
Concomitant Aneurysm	18 (35.3%)
Cancer	17 (33.3%)
Peripheral Vascular Disease	16 (31.4%)
Cardiac Arrhythmia	15 (29.4%)
Carotid Disease	11 (21.6%)
Diabetes Mellitus	11 (21.6%)
Symptomatic Aneurysm	11 (21.6%)
Renal Insufficiency	7 (13.7%)
CABG	6 (11.8%)
CHF	5 (9.8%)
TIA	4 (7.8%)
Erectile Dysfunction	3 (8.8%)
Stroke	3 (5.9%)
Valvular Heart Disease	3 (5.9%)
Paraplegia	1 (2.0%)
Thromboembolic Event	1 (2.0%)
Renal Dialysis	0 (0.0%)
ASA Classification	
I	1 (2.0%)
II	12 (23.5%)
III	30 (58.8%)
IV	8 (15.7%)
V	0 (0.0%)
NYHA Classification	
I	13 (25.5%)
II	23 (45.1%)
III	0 (0.0%)
IV	0 (0.0%)
No Cardiac Disease	14 (27.5%)
Missing	1 (2.0%)
Note: All percentages based on number of subjects enrolled.	

Table 38 lists the initial aneurysm diameter sizes treated.

Table 38. Aneurysm Diameter Distribution

	TAG 08-03
Number of Enrolled Subjects	**51**
Aneurysm Type	
Fusiform Aneurysm (≥ 50 mm)	30 (58.8%)
Saccular Aneurysm	21 (41.2%)
Maximum Aneurysm/Lesion Diameter (mm)	
n	51
Mean (Std Dev)	58.4 (12.3)
Median	56.0
Range	(32.6, 82.5)
Note: All percentages based on number of subjects enrolled.	

Outcomes

The primary objective of the TAG 08-03 study was met. Subjects treated with the GORE® TAG® Device experienced 98% freedom from major device-related events through 1 month post-procedure. The detailed results are separated into Effectiveness, Safety and Treatment Outcomes.

Table 39 lists the number of devices implanted for TAG 08-03. More than 50% of subjects required more than one device (**Table 40**). Some subjects had more than one size device implanted.

Table 39. Devices Implanted[1]

			Initial Procedure	
Proximal Diameter (mm)	Distal Diameter (mm)	Length (cm)	Subjects[2] (N=50) n (%)	Devices[3] (N=89) n (%)
26	26	10	5 (10.0%)	5 (5.6%)
28	28	10	3 (6.0%)	3 (3.4%)
28	28	15	1 (2.0%)	1 (1.1%)
31	26	10	3 (6.0%)	4 (4.5%)
31	31	10	3 (6.0%)	4 (4.5%)
31	31	15	8 (16.0%)	8 (9.0%)
34	34	10	4 (8.0%)	4 (4.5%)
34	34	15	6 (12.0%)	6 (6.7%)
34	34	20	6 (12.0%)	6 (6.7%)
37	37	10	3 (6.0%)	4 (4.5%)
37	37	15	8 (16.0%)	9 (10.1%)
37	37	20	7 (14.0%)	7 (7.9%)
40	40	10	3 (6.0%)	3 (3.4%)
40	40	15	2 (4.0%)	3 (3.4%)
40	40	20	6 (12.0%)	7 (7.9%)
45	45	10	2 (4.0%)	3 (3.4%)
45	45	15	5 (10.0%)	5 (5.6%)
45	45	20	4 (8.0%)	7 (7.9%)

[1] Two GORE® TAG® Device sizes were not implanted as part of this study. Those sizes are the 21mm x 21mm x 10cm and the 26mm x 21mm x 10cm devices.

[2] All percentages based on number of subjects enrolled.

[3] All percentages based on number of devices implanted.

Table 40. Number of Endoprostheses Implanted at Initial Procedure

	TAG 08-03
Number of Enrolled Subjects	**51**
Number of Subjects With Successful Initial Implant	50
Number of Implanted Endoprostheses (Initial Implant)	
0	1 (2.0%)
1	23 (45.1%)
2	18 (35.3%)
3	7 (13.7%)
4	1 (2.0%)
5	1 (2.0%)
n	51
Mean (Std Dev)	1.7 (0.9)
Median	2.0
Range	(0.0, 5.0)

Note: All percentages based on number of subjects enrolled.

The TAG 08-03 procedural outcomes are displayed in **Table 41**. Less than 20% (19.6%) of subjects required a left subclavian artery (LSA) bypass procedure or transposition. The LSA was covered completely in 21.6% of subjects, while 5.9% of subjects had a partially covered LSA.

Table 41. Summary of Procedural Outcomes

	TAG 08-03
Number of Enrolled Subjects	**51**
LSA Procedure	
None	41 (80.4%)
Transposed	1 (2.0%)
Bypassed	9 (17.6%)
Access Site	
Femoral Artery	40 (78.4%)
Iliac Artery	10 (19.6%)
Infrarenal Aorta	1 (2.0%)
Anesthesia Method	
General	50 (98.0%)
Regional	1 (2.0%)
Local	0 (0.0%)
Adjunctive Techniques to Prevent Paraplegia[1]	**27 (52.9%)**
CSF Drainage	18 (66.7%)
Induced Hypertension	3 (11.1%)
Other	6 (22.2%)
Proximal Implantation Zone	
Zone 2	14 (27.5%)
Zone 3 / Zone 4	37 (72.5%)
LSA Coverage	
Complete	11 (21.6%)
Partial	3 (5.9%)
None	37 (72.5%)

Note: All percentages based on number of subjects enrolled except where footnoted.

[1] This count used as denominator for percentages under this heading.

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Effectiveness

The primary endpoint for the TAG 08-03 study was the proportion of subjects with a major device-related event (MDE) through 1 month as compared to a pre-defined rate of success (> 83% freedom from MDE).
Adverse events were characterized by severity, e.g., major or minor, as defined below:

Major

- Requires therapy, minor hospitalization (< 48 hours), or
- Major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), or
- Permanent adverse sequelae, or
- Death

Minor

- Requires no therapy, no consequence, or
- Nominal therapy, no consequence; includes overnight admission for observation only

An imaging core laboratory was used as part of TAG 08-03 to provide an independent assessment of the imaging data collected during this study. Computed tomography films (CTA / CT) and radiographs (X-Ray) for study subjects were sent from the investigative sites to the imaging core laboratory to assess aortic morphology, vascular characteristics, and device integrity. Categories for endoleak are not mutually exclusive and therefore numbers of specific endoleak types may add to more than the total patients with endoleak.

Table 42 summarizes the incidence of site reported major device-related events by study period through 12 months post-procedure. The only major device-related event reported was access failure.

Table 42. Subjects with Major Device-Related Events by Follow-Up Periods (Site Reported)

	Post-Treatment Follow-up Period				
	Procedure	Post-Procedure	1 Month	6 Months	12 Months
Number of Subjects	51	51	49	31	3
Number of Subjects with Imaging Evaluation	51	49	46	27	3
Any Major Device Event	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Vascular access complication (access failure)	1(2.0%)	-	-	-	-

Note: Percentages are based on the number of subjects with CT or MR imaging follow up in the given window.

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days)

MedDRA Version: V13.1

Figure 6 and **Table 43** show the Kaplan-Meier estimates of freedom from major device-related events through 6 months post-procedure.

Figure 6. Freedom from Major Device-Related Events (Site Reported)

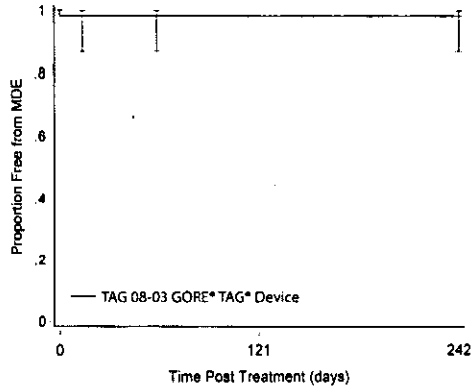

Table 43. Freedom from Major Device-Related Events (Site Reported)

Time Post Treatment (days)	N at Risk at Start of Interval	N Events During Interval [1]	N Censored During Interval [1]	Proportion Free from MDE	95% C.I.[2]
TAG 08-03 GORE® TAG® Device					
0	51	1 (1)	0 (0)	0.980	(0.869, 0.997)
(0-14]	50	0 (1)	1 (1)	0.980	(0.869, 0.997)
(14-59]	49	0 (1)	18 (19)	0.980	(0.869, 0.997)
(59-242]	31	0 (1)	31 (50)	0.980	(0.869, 0.997)

[1] Number in Parenthesis represents cumulative events or censored observations through end of interval.

[2] At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

Table 44 lists all site reported minor device-related events by study period. **Table 45** lists the change in aneurysm diameter based on site reported data. The only minor device related events were three type I and five type II endoleaks, none of which required intervention. Two of the three type I and three of the five type II endoleaks resolved without treatment. There was one increase in aneurysm diameter ≥ 5 mm in the site reported data from a subject with a type II endoleak. No clinical sequelae were noted as a result of these minor endoleaks.

Table 44. Subjects with Minor Device-Related Events by Follow-Up Periods (Site Reported)

	Post-Treatment Follow-up Period				
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**
Number of Subjects	51	51	49	31	3
Number of Subjects with Imaging Evaluation	51	49	46	27	3
Any Minor Device Event	3(5.9%)	0(0.0%)	5(10.9%)	0(0.0%)	0(0.0%)
Stent Graft Endoleak[1]	3(5.9%)	-	5(10.9%)	-	-
Stent-graft endoleak type IA	1(2.0%)	-	2(4.3%)	-	-
Stent-graft endoleak type II	2(3.9%)	-	3(6.5%)	-	-

Note: Percentages are based on the number of subjects with CT or MR imaging follow-up in the given window.

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days)

MedDRA Version: V13.1

[1] Endoleaks are only reported in the time interval in which the event was first observed.

Table 45. Change In Aneurysm Diameter by Follow-Up Periods (Site Data)

	Post-Treatment Follow-up Period					
	6 Months	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
Number of Subjects with Available Data[1]	26	3	0	0	0	0
Change in Aneurysm Diameter From Baseline						
≥ 5mm Decrease	13 (50.0%)	2 (66.7%)	-	-	-	-
No Change	12 (46.2%)	1 (33.3%)	-	-	-	-
≥ 5mm Increase	1 (3.8%)	0 (0.0%)	-	-	-	-

Study period definitions: 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

If multiple observations are contained within a single study window, the observation closest to the visit window date is used.

[1] Subjects must have a baseline (1 Month) and a post-baseline measurement to be available for evaluation. All percentages are based on number of subjects with available data.

Table 46 displays Core Lab reported change in aneurysm diameter. The Core Lab has reported one increase in aneurysm diameter ≥ 5mm.

Table 46. Change in Aneurysm Diameter by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period					
	6 Months	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
Number of Subjects with Available Data[1]	26	3	0	0	0	0
Change in Aneurysm Diameter From Baseline - Axial						
≥ 5mm Decrease	11 (42.3%)	1 (33.3%)	-	-	-	-
No Change	14 (53.8%)	2 (66.7%)	-	-	-	-
≥ 5mm Increase	1 (3.8%)	0 (0.0%)	-	-	-	-
Change in Aneurysm Diameter From Baseline - Orthogonal						
≥ 5mm Decrease	9 (34.6%)	1 (33.3%)	-	-	-	-
No Change	17 (65.4%)	2 (66.7%)	-	-	-	-
≥ 5mm Increase	0 (0.0%)	0 (0.0%)	-	-	-	-
Endoleaks in Subjects with ≥ 5mm Increase in Aneurysm Diameter[2,3]	0 (0.0%)	-	-	-	-	-
Type Ia	-	-	-	-	-	-
Type Ib	-	-	-	-	-	-
Type II	-	-	-	-	-	-
Type III	-	-	-	-	-	-
Type IV	-	-	-	-	-	-
Indeterminate	-	-	-	-	-	-

Study period definitions: 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

If multiple observations are contained within a single study window, the observation closest to the visit window date is used.

[1] Subjects must have a baseline (1 Month) and a post-baseline measurement to be available for evaluation. Percentages of anuerysm diameter change from baseline are based on the number of subjects with available data.

[2] The percentage of endoleaks is among subjects with an increase in aneurysm diameter from either Axial or Orthogonal.

[3] The sum of the type of endoleaks may add up to more than the number of subjects with endoleaks, for subjects can have multiple types.

Table 47 lists all Core Lab observed device-related events by follow-up period. There were three subjects with thrombus observed within the margins of the device at 1 month. The sites did not report thrombus within the margins of the device for these three subjects and no adverse events were noted by the sites for these three subjects due to the thrombus observed by Core Lab. There were nine subjects with an endoleak observed in at least one follow-up period. The Core Lab does not establish whether an endoleak is new or ongoing in their observations. For this reason, it cannot be determined if the endoleaks have resolved or not. It can however be noted which subjects had endoleaks observed in their most recent available follow-up imaging. Three of the nine subjects did not have an endoleak observed on the most recent available follow-up imaging. The remaining six subjects had continued observation of endoleaks on their most recent available follow-up imaging. No increase in aneurysm diameter ≥ 5mm was detected for subjects with these minor endoleaks (**Table 46**). The Core Lab has detected no migrations (prosthesis or inter-component); therefore, a table of that data has not been included in this summary.

Table 47. Subjects with Device-Related Events by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period							
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[1]
Number of Subjects	49	31	3	0	0	0	0	49
Number of Subjects With CT/MR Scan[2]	45	27	3	-	-	-	-	46
Number of Subjects With CT/MR or X-Ray[3]	46	27	3	-	-	-	-	47
Endoleak[4]	7 (15.6%)	5 (18.5%)	1 (33.3%)	-	-	-	-	9 (19.6%)
Type I	1 (2.2%)	1 (3.7%)	0 (0.0%)	-	-	-	-	2 (4.3%)
Type IA	1 (2.2%)	1 (3.7%)	0 (0.0%)	-	-	-	-	2 (4.3%)
Type IB	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type II	2 (4.4%)	2 (7.4%)	0 (0.0%)	-	-	-	-	3 (6.5%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Indeterminate	4 (8.9%)	2 (7.4%)	1 (33.3%)	-	-	-	-	5 (10.9%)
Aortic Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
DTA Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
AAA Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Device Compression	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Thrombus	3 (6.7%)	0 (0.0%)	0 (0.0%)	-	-	-	-	3 (6.5%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)

Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(15-2006 days)

[1] The total column represents the number of subjects with any Core Lab reported event during the study. Events reported in multiple follow-up periods for the same subject are counted once in the total column, so the number of events in the rows of the table may not add up to the number of subjects with that event in the total column.

[2] Denominator used in calculation of percentages for events except Fracture

[3] Denominator used in calculation of percentages for Fracture

[4] Endoleaks are reported in each time interval in which an event was observed.

Safety

The Sponsor monitored safety of the GORE® TAG® Device through collection of site reported adverse events. Sites were instructed to report and classify severity of all adverse events. Serious adverse event data are shown in **Table 48**. All recorded deaths (through January 5, 2011) including cause are displayed in **Table 49**. Additionally the Kaplan-Meier estimate for proportion of subjects free from aneurysm related death through 6 month post-procedure is shown in **Figure 7** and **Table 50**.

Table 48. Serious Adverse Events by Follow-Up Periods

	Post-Treatment Follow-up Period				
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**
Number of Subjects	51	51	49	31	3
Any Event	3(5.9%)	8(15.7%)	3(6.1%)	8(25.8%)	1(33.3%)
Infections and infestations	0(0.0%)	1(2.0%)	0(0.0%)	3(9.7%)	0(0.0%)
Pneumonia	-	-	-	2(6.5%)	-
Gastroenteritis	-	-	-	1(3.2%)	-
Sepsis	-	1(2.0%)	-	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0(0.0%)	0(0.0%)	1(2.0%)	1(3.2%)	0(0.0%)
Colon neoplasm	-	-	-	1(3.2%)	-
Lung carcinoma cell type unspecified stage I	-	-	1(2.0%)	-	-
Blood and lymphatic system disorders	0(0.0%)	0(0.0%)	0(0.0%)	2(6.5%)	0(0.0%)
Anaemia	-	-	-	2(6.5%)	-
Psychiatric disorders	0(0.0%)	2(3.9%)	0(0.0%)	1(3.2%)	0(0.0%)
Mental status changes	-	1(2.0%)	-	1(3.2%)	-
Confusional state	-	1(2.0%)	-	-	-
Nervous system disorders	0(0.0%)	1(2.0%)	1(2.0%)	0(0.0%)	0(0.0%)
Spinal cord ischaemia	-	1(2.0%)	0(0.0%)	-	-
Syringomyelia	-	0(0.0%)	1(2.0%)	-	-
Cardiac disorders	0(0.0%)	2(3.9%)	2(4.1%)	4(12.9%)	0(0.0%)
Myocardial infarction	-	-	1(2.0%)	2(6.5%)	-
Acute myocardial infarction	-	-	1(2.0%)	0(0.0%)	-
Atrial fibrillation	-	1(2.0%)	-	1(3.2%)	-
Coronary artery disease	-	-	-	1(3.2%)	-
Cardiac failure congestive	-	-	-	1(3.2%)	-
Tachycardia	-	1(2.0%)	-	-	-
Vascular disorders	2(3.9%)	2(3.9%)	1(2.0%)	0(0.0%)	1(33.3%)
Haematoma	1(2.0%)	1(2.0%)	-	-	-
Aortic aneurysm	-	-	-	-	1(33.3%)
Hypoperfusion	-	-	1(2.0%)	-	-
Arterial thrombosis limb	1(2.0%)	-	-	-	-
Hypertension	-	1(2.0%)	-	-	-
Hypotension	-	-	1(2.0%)	-	-
Respiratory, thoracic and mediastinal disorders	0(0.0%)	2(3.9%)	0(0.0%)	4(12.9%)	0(0.0%)
Respiratory failure	-	2(3.9%)	-	1(3.2%)	-
Acute respiratory failure	-	0(0.0%)	-	1(3.2%)	-
Pleural effusion	-	1(2.0%)	-	1(3.2%)	-
Pneumothorax	-	0(0.0%)	-	1(3.2%)	-
Pulmonary embolism	-	-	-	2(6.5%)	-
Gastrointestinal disorders	0(0.0%)	2(3.9%)	0(0.0%)	1(3.2%)	0(0.0%)
Colitis	-	1(2.0%)	-	-	-
Abdominal distension	-	1(2.0%)	-	-	-
Peritoneal haemorrhage	-	-	-	1(3.2%)	-

Musculoskeletal and connective tissue disorders	0(0.0%)	1(2.0%)	1(2.0%)	0(0.0%)	0(0.0%)
Muscular weakness	-	-	1(2.0%)	-	-
Back pain	-	1(2.0%)	-	-	-
Renal and urinary disorders	0(0.0%)	1(2.0%)	0(0.0%)	1(3.2%)	0(0.0%)
Renal failure	-	0(0.0%)	-	1(3.2%)	-
Renal failure acute	-	1(2.0%)	-	0(0.0%)	-
General disorders and administration site conditions	0(0.0%)	2(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)
Pyrexia	-	1(2.0%)	-	-	-
Multi-organ failure	-	1(2.0%)	-	-	-
Injury, poisoning and procedural complications	1(2.0%)	2(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)
Anaemia postoperative	0(0.0%)	1(2.0%)	-	-	-
Operative haemorrhage	1(2.0%)	0(0.0%)	-	-	-
Arterial injury	1(2.0%)	-	-	-	-
Extradural haematoma	-	1(2.0%)	-	-	-

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation.

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days)

MedDRA Version: V13.1

Table 49. All-Cause Mortality

Study Day	Cause of Death[1]	Aneurysm Related[1]
8	Multi-organ failure	Yes
32	Acute myocardial infarction	
69	Respiratory failure	Yes
109	Myocardial infarction	
118	Respiratory failure	

[1] As determined by Clinical Events Committee (CEC).

Figure 7. Freedom from Aneurysm-Related Death

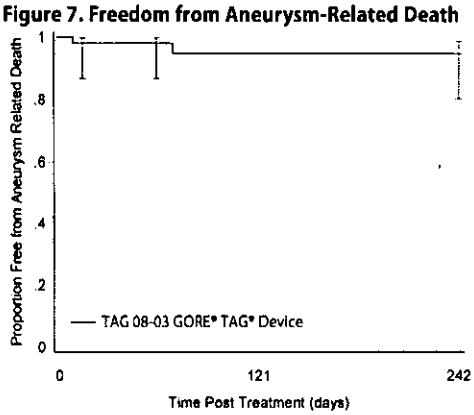

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Table 50. Freedom from Aneurysm-Related Death

Time Post Treatment (days)	N at Risk at Start of Interval	N Events During Interval [1]	N Censored During Interval [1]	Proportion Free from Aneurysm Related Death	95% C.I.[2]
TAG 08-03 GORE® TAG® Device					
0	51	0 (0)	0 (0)	1.000	(1.000, 1.000)
(0-14]	51	1 (1)	1 (1)	0.980	(0.866, 0.997)
(14-59]	49	0 (1)	18 (19)	0.980	(0.866, 0.997)
(59-242]	31	1 (2)	30 (49)	0.948	(0.802, 0.987)

[1] Number in Parenthesis represents cumulative events or censored observations through end of interval

[2] At each time interval the 95% confidence intervals are provided to describe the variability associated with the estimated proportion of subjects remaining event free through that interval. The confidence intervals are produced using the complimentary log (log) transformation applied to the cumulative hazard function.

Treatment Outcomes

Table 51 shows the treatment outcomes for the TAG 08-03 study subjects. Subjects in TAG 08-03 had 100% procedural survival and 98% hospital survival. The median procedural time was less than 2 hours with a low median blood loss of 150 mL. Subjects remained in the hospital for a median length of stay of 4 days with 74.5% of subjects spending a median of 1.9 days in the ICU during that time. The time to return to normal daily activities was 33.7 days on average.

Table 51. Treatment Outcomes

	TAG 08-03
Number of Enrolled Subjects	51
Procedure Time (minutes)	
n	51
Mean (Std Dev)	125.0 (56.2)
Median	118.0
Range	(45.0, 284.0)
Blood Loss (mL)	
n	51
Mean (Std Dev)	276.4 (403.5)
Median	150.0
Range	(0.0, 2250)
Procedure Survival	51 (100.0%)
Hospitalization Duration (Days)	
n	51
Mean (Std Dev)	6.2 (9.7)
Median	4.0
Range	(1.0, 68.0)
ICU Stay	
Yes	38 (74.5%)
No	13 (25.5%)
ICU Days	
n	38
Mean (Std Dev)	2.5 (3.7)
Median	1.9
Range	(0.1, 22.6)
Intubation	
Yes	45 (88.2%)
No	6 (11.8%)
Return to Normal Daily Activities (Days)	
n	46
Mean (Std Dev)	33.7 (31.3)
Median	30.5
Range	(3.0, 212.0)
Hospital Survival	50 (98.0%)
Note: All percentages based on number of subjects enrolled.	

Conclusion: TAG 08-03

The primary endpoint of the TAG 08-03 study was met; 98% of subjects treated with the GORE® TAG® Thoracic Endoprosthesis remain free from major device-related events through 1 month post-procedure. The incidence of short term major adverse event in the TAG 08-03 study was similar to the TAG 99-01 and TAG 03-03 studies. No new safety risks were identified with the use of the GORE® TAG® Device in the treatment of DTA aneurysms during the TAG 08-03 study. There were no strokes or aortic ruptures reported. The safety results with the GORE® TAG® Device in the TAG 08-03 study are similar to historical study results.

Use of the GORE® TAG® Thoracic Endoprosthesis in Traumatic Aortic Transections of the Descending Thoracic Aorta: TAG 08-02

TAG 08-02 Summary

TAG 08-02 was a non-randomized, multi-center clinical study designed to evaluate the further modified GORE® TAG® Thoracic Endoprosthesis for the treatment of traumatic aortic transections of the DTA. Fifty-one (51) subjects were enrolled at 21 investigative sites. Subjects were assessed at pre-treatment, treatment, and hospital discharge and returned for follow-up visits at 1 month with additional visits at 6, 12, 24, 36, 48, and 60 months post-treatment.

Site reported data is presented in this summary. An imaging core laboratory provided an independent assessment of the imaging data collected during this study; the core laboratory data is also presented in this summary. Clinical events were adjudicated by a clinical events committee, and safety was monitored by a data safety monitoring board. Data lock for the site reported and core laboratory data presented in this summary was 28 May 2011.

The primary safety endpoint of the study was all-cause mortality incidence through 30 days post-treatment. The primary efficacy endpoint was freedom from an MDE through the 1 month follow-up visit. Enrollment began in December 2009 and was completed in January 2011. Annual follow-up through five years post-treatment is ongoing.

Table 52 provides the disposition and compliance for subjects enrolled into the TAG 08-02 clinical study. Available subjects are defined as those that are alive and participating in the study for that follow-up period. For a given study period, data presented include the number of subjects eligible for follow-up (e.g., number eligible from previous period minus subject deaths, subjects discontinued or not yet due for their next follow-up visit).

Table 52. Subject Disposition and Compliance by Study Period

		Follow-up Compliance			Events Prior to Next Interval		
Study Period	Eligible for follow-up[1]	Subjects with Visit in Window	CT Scan performed[2,3]	X-Ray performed[2,3]	Death[2]	Discontinued[2]	Not Due for Next F/U[2]
Procedure	51	-	-	-	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Procedure	51	-	-	-	3 (5.9%)	0 (0.0%)	0 (0.0%)
1 Month	48	47 (97.9%)	45 (93.8%)	43 (89.6%)	2 (4.2%)	0 (0.0%)	0 (0.0%)
6 Months	46	26 (56.5%)	23 (50.0%)	24 (52.2%)	1 (2.2%)	0 (0.0%)	23 (50.0%)
12 Months	22	7 (31.8%)	6 (27.3%)	6 (27.3%)	0 (0.0%)	0 (0.0%)	22 (100.0%)
24 Months	0	-	-	-	-	-	-
36 Months	0	-	-	-	-	-	-
48 Months	0	-	-	-	-	-	-
60 Months	0	-	-	-	-	-	-

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

[1] Subjects are considered eligible for follow-up if time on the study is on or after the first day of the given time window and they have not discontinued or died prior to the start of the interval.

[2] Percentages are based on number of subjects in visit window. Compliance is based on site reported imaging assessments.

[3] Refer to individual results tables for the number of subjects with adequate imaging to assess the parameters provided in that specific results table.

Subject Characteristics

Tables 53 - 54 list TAG 08-02 subject demographics and pre-treatment medical history.

Table 53. Subject Demographics

	TAG 08-02
Number of Enrolled Subjects	51
Gender	
Male	34 (66.7%)
Female	17 (33.3%)
Ethnicity	
Not Hispanic or Latino	49 (96.1%)
Hispanic or Latino	2 (3.9%)
Race	
White or Caucasian	42 (82.4%)
Black or African American	5 (9.8%)
Asian / Oriental	2 (3.9%)
American Indian or Alaskan Native	1 (2.0%)
Native Hawaiian or Other Pacific Islander	1 (2.0%)
Middle Eastern	0 (0.0%)
Other	0 (0.0%)
Unknown	0 (0.0%)
Age (yrs)	
n	51
Mean (Std Dev)	44.1 (19.9)
Median	40.0
Range	(21.0, 87.0)
Weight (kg)	
n	51
Mean (Std Dev)	90.4 (20.0)
Median	85.4
Range	(63.0, 150.0)
Height (cm)	
n	51
Mean (Std Dev)	171.8 (10.7)
Median	171.5
Range	(152.4, 198.1)
Note: All percentages based on number of subjects enrolled.	

Table 54. Subject Pre-Treatment Medical History

	TAG 08-02
Number of Enrolled Subjects	51
Cigarette Smoking	15 (29.4%)
Hypertension	13 (25.5%)
Hypercholesterolemia	7 (13.7%)
CAD	4 (7.8%)
Diabetes Mellitus	4 (7.8%)
COPD	3 (5.9%)
CABG	2 (3.9%)
Renal Insufficiency	2 (3.9%)
CHF	1 (2.0%)
Carotid Disease	1 (2.0%)
Stroke	1 (2.0%)
TIA	1 (2.0%)
Peripheral Vascular Disease	0 (0.0%)
ASA Classification	
I	5 (9.8%)
II	5 (9.8%)
III	10 (19.6%)
IV	31 (60.8%)
V	0 (0.0%)
Note: All percentages based on number of subjects enrolled.	

Outcomes

Subjects in the TAG 08-02 study experienced a 30 day mortality rate of 7.8%, 100% freedom from major device-related events through 1 month post-procedure, and 100% procedural survival. The detailed results are separated into Safety, Effectiveness and Treatment Outcomes.

Table 55 lists the distribution of devices implanted for TAG 08-02. More than 88% of subjects required only a single device **(Table 56)**.

Table 55. Devices Implanted[1]

			Initial Procedure	
Proximal Diameter (mm)	**Distal Diameter (mm)**	**Length (cm)**	**Subjects[2] (N=51) n (%)**	**Devices[3] (N=57) n (%)**
21	21	10	5 (9.8%)	5 (8.8%)
26	21	10	10 (19.6%)	11 (19.3%)
26	26	10	11 (21.6%)	12 (21.1%)
28	28	10	8 (15.7%)	10 (17.5%)
31	26	10	8 (15.7%)	8 (14.0%)
31	31	10	4 (7.8%)	5 (8.8%)
34	34	10	4 (7.8%)	4 (7.0%)
37	37	10	1 (2.0%)	2 (3.5%)

[1] Only 10cm length GORE® TAG® Device sizes were provided to sites for this study; therefore, no 15cm or 20cm devices were implanted. Two diameter GORE® TAG® Devices were not implanted as part of this study. Those diameters are the 40mm and the 45mm devices.

[2] All percentages based on number of subjects enrolled.

[3] All percentages based on number of devices implanted.

Table 56. Number of Endoprostheses Implanted at Initial Procedure

	TAG 08-02
Number of Enrolled Subjects	51
Number of Subjects With Successful Initial Implant	51
Number of Implanted Endoprostheses (Initial Implant)	
1	45 (88.2%)
2	6 (11.8%)
n	51
Mean (Std Dev)	1.1 (0.3)
Median	1.0
Range	(1.0, 2.0)
Note: All percentages based on number of subjects enrolled.	

The TAG 08-02 procedural outcomes are displayed in **Table 57**. The LSA was completely or partially covered in 62.8% of study subjects with only 5.9% of subjects receiving an LSA bypass or transposition.

Table 57. Summary of Procedural Outcomes

	TAG 08-02
Number of Enrolled Subjects	**51**
LSA Procedure	
None	48 (94.1%)
Transposed	1 (2.0%)
Bypassed	2 (3.9%)
Access Site	
Femoral Artery	49 (96.1%)
Iliac Artery	1 (2.0%)
Infrarenal Aorta	1 (2.0%)
Anesthesia Method	
General	47 (92.2%)
Regional	1 (2.0%)
Local	3 (5.9%)
Adjunctive Techniques to Prevent Paraplegia[1]	**4 (7.8%)**
CSF Drainage	1 (25.0%)
Induced Hypertension	2 (50.0%)
Other	1 (25.0%)
Proximal Implantation Zone	
Zone 2	32 (62.7%)
Zone 3 / Zone 4	19 (37.3%)
LSA Coverage	
Complete	17 (33.3%)
Partial	15 (29.4%)
None	19 (37.3%)
Note: All percentages based on number of subjects enrolled except where footnoted.	
[1] This count used as denominator for percentages under this heading.	

Safety

The Sponsor evaluated safety of the GORE® TAG® Device through collection of site reported adverse events. Incidence of all-cause mortality through 30 days post-treatment is displayed in **Table 58**. All recorded deaths (through April 28, 2011) including cause are displayed in **Table 59**. Sites were instructed to report and classify severity of all adverse events. Data from the TAG 08-02 study show a low incidence of serious adverse events (**Table 60**). There were no paraplegia, retrograde dissections, or aortic ruptures reported. There was only one serious stroke reported.

Table 58. All-Cause Mortality Through 30 Days Post-Treatment

Enrolled	Eligible for Primary Endpoint Analysis	Number of 30 Day Deaths	30 Day Mortality Percentage (95% CI)
51	51	4	7.8% (3.1%, 18.5%)

Table 59. All-Cause Mortality

Study Day	Cause of Death	Related to Device or Procedure[1]
1	Splenic haemorrhage	Unrelated to device or endovascular procedure
2	Cardio-respiratory arrest	Unrelated to device or endovascular procedure
12	Respiratory failure	Unrelated to device or endovascular procedure
17	Shock	Unrelated to device or endovascular procedure
57	Traumatic brain injury	Unrelated to device or endovascular procedure
204	Drug toxicity	Unrelated to device or endovascular procedure

[1] As adjudicated by the CEC

Table 60. Serious Adverse Events by Follow-Up Periods

	Post-Treatment Follow-up Period				
	Procedure	Post-Procedure	1 Month	6 Months	12 Months
Number of Subjects	51	51	48	35	8
Any Event	5(9.8%)	18(35.3%)	6(12.5%)	4(11.4%)	1(12.5%)
Infections and infestations	0(0.0%)	4(7.8%)	3(6.3%)	0(0.0%)	1(12.5%)
Postoperative wound infection	-	0(0.0%)	1(2.1%)	-	-
Respiratory tract infection	-	1(2.0%)	0(0.0%)	-	-
Wound infection	-	0(0.0%)	1(2.1%)	-	-
Pneumonia	-	1(2.0%)	1(2.1%)	-	-
Cellulitis	-	-	-	-	1(12.5%)
Enterococcal infection	-	1(2.0%)	-	-	-
Septic shock	-	1(2.0%)	-	-	-
Skin infection	-	1(2.0%)	-	-	-
Wound infection staphylococcal	-	-	1(2.1%)	-	-
Blood and lymphatic system disorders	0(0.0%)	3(5.9%)	0(0.0%)	0(0.0%)	0(0.0%)
Anaemia	-	1(2.0%)	-	-	-
Leukocytosis	-	1(2.0%)	-	-	-
Splenic haemorrhage	-	1(2.0%)	-	-	-
Metabolism and nutrition disorders	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Abnormal weight gain	1(2.0%)	-	-	-	-
Nervous system disorders	1(2.0%)	2(3.9%)	0(0.0%)	1(2.9%)	0(0.0%)
Ischaemic stroke	-	1(2.0%)	-	-	-
Cerebral hypoperfusion	-	1(2.0%)	-	-	-
Hypoxic-ischaemic encephalopathy	1(2.0%)	-	-	-	-
Headache	-	-	-	1(2.9%)	-
Cardiac disorders	0(0.0%)	3(5.9%)	2(4.2%)	0(0.0%)	0(0.0%)
Atrial fibrillation	-	1(2.0%)	0(0.0%)	-	-
Supraventricular tachycardia	-	0(0.0%)	1(2.1%)	-	-
Angina pectoris	-	1(2.0%)	-	-	-
Pericardial effusion	-	-	1(2.1%)	-	-
Tachycardia	-	1(2.0%)	-	-	-
Cardio-respiratory arrest	-	1(2.0%)	-	-	-
Vascular disorders	2(3.9%)	1(2.0%)	1(2.1%)	2(5.7%)	0(0.0%)
Hypotension	1(2.0%)	1(2.0%)	-	1(2.9%)	-
Shock	-	-	1(2.1%)	-	-
Haemodynamic instability	1(2.0%)	-	-	-	-
Intermittent claudication	-	-	-	1(2.9%)	-
Hypertension	1(2.0%)	-	-	-	-

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Respiratory, thoracic and mediastinal disorders	3(5.9%)	8(15.7%)	1(2.1%)	0(0.0%)	0(0.0%)
Pleural effusion	-	3(5.9%)	-	-	-
Pneumothorax	-	1(2.0%)	-	-	-
Respiratory failure	1(2.0%)	2(3.9%)	-	-	-
Acute respiratory failure	0(0.0%)	1(2.0%)	-	-	-
Hypoxia	2(3.9%)	-	-	-	-
Dyspnoea	-	1(2.0%)	0(0.0%)	-	-
Respiratory distress	-	0(0.0%)	1(2.1%)	-	-
Acute respiratory distress syndrome	-	1(2.0%)	-	-	-
Gastrointestinal disorders	1(2.0%)	1(2.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Ileus	1(2.0%)	1(2.0%)	-	-	-
Haematemesis	-	1(2.0%)	-	-	-
Musculoskeletal and connective tissue disorders	0(0.0%)	1(2.0%)	0(0.0%)	1(2.9%)	0(0.0%)
Joint contracture	-	1(2.0%)	-	-	-
Fracture nonunion	-	-	-	1(2.9%)	-
Renal and urinary disorders	0(0.0%)	2(3.9%)	1(2.1%)	0(0.0%)	0(0.0%)
Anuria	-	2(3.9%)	0(0.0%)	-	-
Renal failure	-	0(0.0%)	1(2.1%)	-	-
General disorders and administration site conditions	1(2.0%)	2(3.9%)	0(0.0%)	0(0.0%)	0(0.0%)
Pyrexia	1(2.0%)	1(2.0%)	-	-	-
Non-cardiac chest pain	-	1(2.0%)	-	-	-
Investigations	0(0.0%)	2(3.9%)	1(2.1%)	0(0.0%)	0(0.0%)
Heart rate increased	-	1(2.0%)	-	-	-
Blood culture positive	-	-	1(2.1%)	-	-
Haematocrit decreased	-	1(2.0%)	-	-	-
Injury, poisoning and procedural complications	1(2.0%)	2(3.9%)	0(0.0%)	1(2.9%)	0(0.0%)
Splenic injury	-	1(2.0%)	-	-	-
Traumatic liver injury	-	1(2.0%)	-	-	-
Traumatic brain injury	1(2.0%)	-	-	-	-
Fat embolism	-	1(2.0%)	-	-	-
Drug toxicity	-	-	-	1(2.9%)	-

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation.

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days)

MedDRA Version: V13.1

Effectiveness

The Sponsor evaluated effectiveness of the GORE® TAG® Device through evaluation of site reported data and Core Lab data. Adverse events were characterized by severity, e.g., major or minor, as defined below:

Major

- Requires therapy, minor hospitalization (< 48 hours), or
- Major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 hours), or
- Permanent adverse sequelae, or
- Death

Minor

- Requires no therapy, no consequence, or
- Nominal therapy, no consequence; includes overnight admission for observation only

An imaging core laboratory was used as part of TAG 08-02 to provide an independent assessment of the imaging data collected during this study. Computed tomography films (CTA / CT) and radiographs (X-Ray) for study subjects were sent from the investigative sites to the imaging core laboratory to assess aortic morphology, vascular characteristics, and device integrity. Categories for endoleak are not mutually exclusive and therefore numbers of specific endoleak types may add to more than the total patients with endoleak.

There were no major device-related events reported (notably, no device compression, wire fractures, erosions/extrusions, conversions, or major endoleaks); therefore, there is no table of this data. There were only two minor device-related events reported (endoleaks) **(Table 61)**. There were no increases in lesion diameter based on the site reported data **(Table 62)**.

Table 61. Subjects with Minor Device-Related Events by Follow-Up Periods (Site Reported)

	Post-Treatment Follow-up Period				
	Procedure	**Post-Procedure**	**1 Month**	**6 Months**	**12 Months**
Number of Subjects	51	51	48	35	8
Number of Subjects with Imaging Evaluation	51	40	45	24	6
Any Minor Device Event	1(2.0%)	1(2.5%)	0(0.0%)	0(0.0%)	0(0.0%)
Stent Graft Endoleak[1]	1(2.0%)	1(2.5%)	-	-	-
Stent-graft endoleak type II	0(0.0%)	1(2.5%)	-	-	-
Stent-graft endoleak type III	1(2.0%)	0(0.0%)	-	-	-

Study period definitions: Procedure(0-0 days) Post-Procedure(1-14 days) 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days)

MedDRA Version: V13.1

[1] Endoleaks are only reported in the time interval in which the event was first observed.

Note: Percentages are based on the number of subjects with an imaging evaluation in the given window.

Table 62. Change In Lesion Diameter by Follow-Up Periods (Site Data)

	Post-Treatment Follow-up Period					
	6 Months	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
Number of Subjects with Available Data[1]	22	5	0	0	0	0
Change in Lesion Diameter From Baseline						
≥ 5mm Decrease	1 (4.5%)	0 (0.0%)	-	-	-	-
No Change	21 (95.5%)	5 (100.0%)	-	-	-	-
≥ 5mm Increase	0 (0.0%)	0 (0.0%)	-	-	-	-

Study period definitions: 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

If multiple observations are contained within a single study window, the observation closest to the visit window date is used.

[1] Subjects must have a baseline (1 Month) and a post-baseline measurement to be available for evaluation. All percentages are based on number of subjects with available data.

Table 63 displays Core Lab reported change in lesion diameter. The Core Lab has reported one increase in lesion diameter ≥ 5mm.

Table 63. Change in Lesion Diameter by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period					
	6 Months	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**
Number of Subjects with Available Data[1]	22	6	0	0	0	0
Change in Lesion Diameter From Baseline - Axial						
≥ 5mm Decrease	1 (4.5%)	3 (50.0%)	-	-	-	-
No Change	21 (95.5%)	2 (33.3%)	-	-	-	-
≥ 5mm Increase	0 (0.0%)	1 (16.7%)	-	-	-	-
Change in Lesion Diameter From Baseline - Orthogonal						
≥ 5mm Decrease	0 (0.0%)	0 (0.0%)	-	-	-	-
No Change	22 (100.0%)	6 (100.0%)	-	-	-	-
≥ 5mm Increase	0 (0.0%)	0 (0.0%)	-	-	-	-
Endoleaks in Subjects with >= 5mm Increase in Lesion Diameter[2,3]	-	0 (0.0%)	-	-	-	-
Type Ia	-	-	-	-	-	-
Type Ib	-	-	-	-	-	-
Type II	-	-	-	-	-	-
Type III	-	-	-	-	-	-
Type IV	-	-	-	-	-	-
Indeterminate	-	-	-	-	-	-

Study period definitions: 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days)

If multiple observations are contained within a single study window, the observation closest to the visit window date is used.

[1] Subjects must have a baseline (1 Month) and a post-baseline measurement to be available for evaluation. Percentages of lesion diameter change from baseline are based on the number of subjects with available data.

[2] The percentage of endoleaks is among subjects with an increase in aneurysm diameter from either Axial or Orthogonal.

[3] The sum of the type of endoleaks may add up to more than the number of subjects with endoleaks, for subjects can have multiple types.

There were no migrations in the site reported data. The Core Lab has reported one migration ≥ 10mm **(Table 64)**.

Table 64. Subjects with Migrations by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period							
	1 Month	**6 Months**	**12 Months**	**24 Months**	**36 Months**	**48 Months**	**60 Months**	**Total**
Number of Subjects	48	35	8	0	0	0	0	48
Number of Subjects With CT/MR or X-Ray[1]	45	24	6	-	-	-	-	46
Number of Subjects With CT/MR or X-Ray and >1 Device Implanted[2]	4	1	0	-	-	-	-	4
Migration	0 (0.0%)	1 (4.2%)	0 (0.0%)	-	-	-	-	1 (2.2%)
Prosthesis Migration	0 (0.0%)	1 (4.2%)	0 (0.0%)	-	-	-	-	1 (2.2%)
Intercomponent Migration	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)

Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(15-2006 days)

[1] Denominator used in calculation of percentages for Migration and Prosthesis Migration

[2] Denominator used in calculation of percentages for Intercomponent Migration

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Table 65 lists all other Core Lab observed device-related events by follow-up period.

Table 65. Subjects with Device-Related Events by Follow-Up Periods (Core Lab)

	Post-Treatment Follow-up Period							
	1 Month	6 Months	12 Months	24 Months	36 Months	48 Months	60 Months	Total[1]
Number of Subjects	48	35	8	0	0	0	0	48
Number of Subjects With CT/MR Scan[2]	45	23	6	-	-	-	-	46
Number of Subjects With CT/MR or X-Ray[3]	45	24	6	-	-	-	-	46
Endoleak[4]	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type IA	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type IB	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type III	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Type IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Indeterminate	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Aortic Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
DTA Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
AAA Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Fracture	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Extrusion/Erosion	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Lumen Obstruction	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Device Compression	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Thrombus	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	-	-	-	0 (0.0%)

Study period definitions: 1 Month(15-59 days) 6 Months(60-242 days) 12 Months(243-546 days) 24 Months(547-911 days) 36 Months(912-1275 days) 48 Months(1276-1640 days) 60 Months(1641-2006 days) Total(15-2006 days)

[1] The total column represents the number of subjects with any Core Lab reported event during the study. Events reported in multiple follow-up periods for the same subject are counted once in the total column, so the number of events in the rows of the table may not add up to the number of subjects with that event in the total column.

[2] Denominator used in calculation of percentages for events except Fracture

[3] Denominator used in calculation of percentages for Fracture

[4] Endoleaks are reported in each time interval in which an event was observed.

Treatment Outcomes

Table 66 shows the treatment outcomes for the TAG 08-02 study subjects. Subjects in TAG 08-02 had 100% procedural survival with hospital survival of 92.2%. The median procedural time was 91 minutes with a median blood loss of 100 mL. Subjects remained in the hospital for a median length of stay of 13 days with a median of 5.4 days in the ICU during that time.

Table 66. Treatment Outcomes

	TAG 08-02
Number of Enrolled Subjects	51
Procedure Time (minutes)	
n	51
Mean (Std Dev)	104.9 (44.9)
Median	91.0
Range	(35.0, 232.0)
Blood Loss (mL)	
n	51
Mean (Std Dev)	147.9 (203.1)
Median	100.0
Range	(0.0, 1400)
Procedure Survival	51 (100.0%)
Hospitalization Duration (Days)	
n	51
Mean (Std Dev)	14.6 (12.3)
Median	13.0
Range	(2.0, 73.0)
ICU Stay	
Yes	51 (100.0%)
No	0 (0.0%)
ICU Days	
n	51
Mean (Std Dev)	8.2 (7.9)
Median	5.4
Range	(0.7, 36.5)
Intubation	
Yes	40 (78.4%)
No	11 (21.6%)
Ventilator Days	
n	50
Mean (Std Dev)	6.5 (11.8)
Median	1.0
Range	(0.0, 60.0)
Hospital Survival	47 (92.2%)
Note: All percentages based on number of subjects enrolled.	

Conclusion: TAG 08-02

Subjects treated with the GORE® TAG® Thoracic Endoprosthesis experienced a 30 day all-cause mortality rate of 7.8%, experienced procedural and hospital survival rates of 100% and 92.2% respectively, and remain 100% free from major device-related events through 1 month post-procedure. There were no device compressions, fractures, device occlusions, major endoleaks, reinterventions, surgical conversions, or device or endovascular procedure related deaths. Safety and efficacy data and treatment outcomes from the TAG 08-02 study provide evidence that the GORE® TAG® Thoracic Endoprosthesis is a reasonably safe and effective treatment option for traumatic aortic transections of the descending thoracic aorta.

SUMMARY OF POST-APPROVAL STUDIES

As a condition of US FDA pre-market approval, W. L. Gore & Associates was committed to conducting a post-approval study to evaluate the long-term performance of the GORE® TAG® Thoracic Endoprosthesis in the primary treatment of descending thoracic aortic (DTA) aneurysms and to assess the GORE® TAG® Device Physician Training Program. This study would enroll 150 subjects at up to 35 sites prospectively or retrospectively treated by clinicians participating in the training program.

The TAG 05-02 protocol was designed to evaluate the long-term performance of the GORE® TAG® Thoracic Endoprosthesis by demonstrating that aneurysm-related death for subjects treated with the device is not inferior to historical control subjects treated with open surgical repair. In addition, a subset of MAEs including stroke, paraplegia, reintervention, and aneurysm-related death would be evaluated in subjects treated with the device and historical control subjects treated with open surgical repair.

The study was designed to assess the effectiveness of the training program by considering the incidence of major device-related events (MDEs) through 30 days. MDEs include: unplanned branch vessel occlusion, endoleak, deployment failure, lumen obstruction, prosthesis material failure, aneurysm rupture, extrusion/erosion, prosthesis migration, prosthesis realignment and other device-related complications as specified by the investigator.

TAG 05-02 has completed enrollment, and all of the subjects enrolled into the study have passed the 30 day post-treatment follow-up interval. A summary of the results of the training program assessment is below, while evaluation of the long-term performance of the device continues for all eligible subjects.

GORE® TAG® Device Physician Training Program

The GORE® TAG® Device Physician Training Program is categorized into four tiers. These tiers relate to a physician's prior endovascular experience with Tier I physicians being the most experienced and Tier IV physicians the least experienced. The objective of the training program is to adequately prepare qualifying physicians to safely implant the GORE® TAG® Thoracic Endoprosthesis in compliance with these Instructions for Use.

One hundred fifty subjects treated by physicians in Tiers I - III were evaluated. One subject treated by a Tier IV physician was included as a Tier III subject for ease of analysis. Eleven (7.3%) subjects overall experienced one or more MDEs during the 30 day follow-up visit window. These MDEs were equally distributed across tiers.

There was no significant difference among the three tiers in percentage of subjects free from MDEs through the 30 day follow-up visit window, the percentage of which ranged from 91.2% to 93.8%.

In conclusion, the short term results reported suggest that the GORE® TAG® Device Physician Training Program is effective at preparing physicians of varying experience levels to use the GORE® TAG® Device.

PATIENT SELECTION AND TREATMENT (SEE WARNINGS AND PRECAUTIONS)

Gore recommends that the GORE® TAG® Thoracic Endoprosthesis be used in accordance with the Sizing Table (**Table 67**).

- The GORE® TAG® Thoracic Endoprosthesis is designed to treat:
  - Proximal and distal aortic neck lengths of ≥ 20 mm,
  - Proximal and distal aortic neck inner diameters between 16 and 42 mm.
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (**Table 67**) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.
- All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters / lengths) are not certain. This approach allows for greater intra-operative flexibility to achieve optimal procedural outcomes.

The risks and benefits discussed in SUMMARY OF US CLINICAL STUDIES should be carefully considered for each patient before use of the GORE® TAG® Thoracic Endoprosthesis.

Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary, renal)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- Risk of lesion rupture versus the risk of treatment with the GORE® TAG® Thoracic Endoprosthesis as listed in *Potential Device Or Procedure Related Adverse Events* in the WARNINGS AND PRECAUTIONS section.
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories
- The final treatment decision is at the discretion of the physician and patient

The TAG 04-01 study protocol did not specify any differences in peri-operative care of patients with ruptured DTA aneurysm as compared to the TAG 99-01, TAG 03-03 and TAG 05-02 aneurysm trials. Medical management, anesthetic protocol, and all aspects of peri-operative care for these patients were left to the discretion of the implanting physician. Case planning guidelines were identical to those outlined for the treatment of DTA aneurysm in the GORE® TAG® Device Instructions for Use (IFU).

Follow-up imaging requirements were also identical to the aneurysm patient guidelines outlined in the IFU. The primary outcome differences that were noted between patients with ruptured vs. intact DTA aneurysm were higher mortality, longer convalescence (median 7 day hospitalization vs. 3) and higher endoleak incidence (although most were incidentally noted). Compared to intact aneurysm patients, patients with ruptured DTA presented emergently, were older (median 79 years vs. 72-74), and were frequently symptomatic (chest and back pain most common).

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PATIENT COUNSELING INFORMATION

The physician and patient should review the risks and benefits when discussing this endovascular device and procedure including:

- Risk and benefit differences between endovascular repair and open surgical repair
- Potential advantages and disadvantages of open surgical repair
- Potential advantages and disadvantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair may be required after initial endovascular repair

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment and compliance to post-operative follow-up as necessary to ensure continuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- **The long-term safety and effectiveness of endovascular repair has not been established.** Physicians should advise all patients that this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging lesions) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms, e.g., pain, numbness, weakness (see IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP).
- Regular follow-up including imaging of the device should be performed at least every 12 months for all patients and at least every 6 to 12 months for patients with known endoleaks or lesion enlargement for the duration of the implant (see IMAGING GUIDELINES AND POST- OPERATIVE FOLLOW-UP).
- Physicians must advise all patients that it is important to seek prompt medical attention if he / she experiences signs of device occlusion, lesion enlargement or rupture. Signs of device occlusion include pain in the chest, abdomen or hip(s) or leg(s) during but may not be limited to activity. Rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs, any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.

Physicians are encouraged to refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, lesion enlargement, fracture, potential for reintervention and open surgical conversion, rupture and death (See *Potential Device Or Procedure Related Adverse Events* in the WARNINGS AND PRECAUTIONS section). Physicians are encouraged to complete the Patient Wallet Card and give it to the patient so that he / she can carry it with them at all times. The patient should refer to the wallet card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

HOW SUPPLIED

The GORE® TAG® Thoracic Endoprosthesis and introducer sheath caps are supplied sterile and non-pyrogenic.

Storage and Handling

- Do not resterilize; for single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the "use by" (expiration) date printed on the label.
- Store in a cool, dry place.

CLINICAL USE INFORMATION

WARNING: Always have a surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

WARNING: The GORE® TAG® Thoracic Endoprosthesis should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program.

The recommended skill / knowledge requirements for physicians using the GORE® TAG® Thoracic Endoprosthesis are outlined below:

Patient Selection

- Knowledge of the natural history of thoracic aortic disease and co-morbidities associated with endovascular repair of the descending thoracic aorta.
- Knowledge of radiographic image interpretation, device selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Vascular access techniques
- Guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of contrast agents
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

Materials Required for Device Placement

- GORE® TAG® Thoracic Endoprosthesis in the appropriate diameter(s) and length(s) (**Table 67**)
- GORE® Introducer Sheath with Silicone Pinch Valve Cap (two supplied with endoprosthesis)
- GORE® Tri-Lobe Balloon Catheter (supplied separately)
- GORE® Introducer Sheath with Silicone Pinch Valve or GORE® DrySeal Sheath of appropriate french size for the selected endoprosthesis diameter (supplied separately) (**Table 67**)
- Hemostatic vascular clamp with soft jaws (for use with GORE® Introducer Sheath with Silicone Pinch Valve)
- 0.035" (0.89 mm) Medi-Tech Amplatz Super Stiff Guidewire or equivalent, 250 cm or longer
- Heparin and heparinized saline solution
- Contrast agents
- Sterile syringes
- 3-way stopcock
- Appropriate diagnostic catheters and accessories

Sizing

Table 67 indicates the appropriate diameter prosthesis for the intended aortic neck diameter. Aortic neck diameters should be measured from axial CTA films and should consist only of the flow lumen (including thrombus) and not the vessel wall. Three diameter measurements are required for both the proximal and distal necks (**Figure 9**). All measurements per neck must be within one Intended Aortic Inner Diameter range, as listed in **Table 67**. Appropriate oversizing (6-33%) is built into the recommended sizes. Therefore, do not incorporate additional oversizing in the selection of the endoprosthesis.

Table 67. Sizing Guide

Labeled Diameter[1] (mm)	Partially Uncovered Proximal Stent Length (mm)	Intended Aortic Diameter[2] (mm)	Available Endoprosthesis Lengths[1, 3] (cm)	Recommended Introducer Sheath Size[4] (Fr)
21	3	16 - 19.5	10	18
26	4	19.5 - 24	10	20
28	4	22 - 26	10, 15	
31	4	24 - 29	10, 15	22
34	5	27 - 32	10, 15, 20	
37	5	29 - 34	10, 15, 20	24
40	6	31 - 37	10, 15, 20	
45	6.5	34 - 42	10, 15, 20	
26 (proximal) 21 (distal)	4	19.5 - 24 (proximal) 16 - 19.5 (distal)	10	20
31 (proximal) 26 (distal)	4	24 - 29 (proximal) 19.5 - 24 (distal)	10	22

[1] All dimensions are nominal.

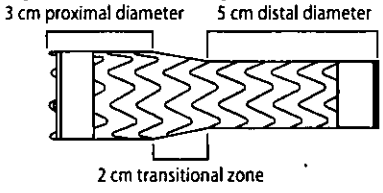
[2] Appropriate oversizing is built into the recommended sizes.

[3] A minimum of 20 mm non-aneurysmal aortic neck length is required both proximal and distal to the lesion. The length of the patient's lesion, plus a minimum of 4.0 cm for the non-aneurysmal necks, should be used when calculating the required endoprosthesis length. More than one endoprosthesis may be needed to cover the entire treatment area.

[4] The GORE® TAG® Thoracic Endoprosthesis is only compatible with either the GORE® Introducer Sheath with Silicone Pinch Valve or the GORE® DrySeal Sheath. Compatibility with other sheaths has not been established. Please refer to specific sheath IFU for instructions for use.

Figure 8 illustrates the construct of the tapered configurations listed in **Table 67**.

Figure 8. Tapered Configurations



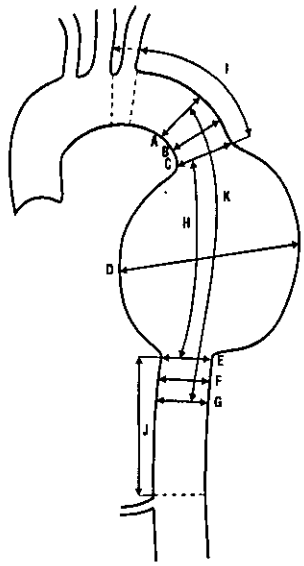
DIRECTIONS FOR USE

Anatomical Requirements

- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories.
- Proximal and distal aortic neck lengths should be a minimum of 20 mm.
- Aortic neck inner diameters (ID) in the range of 16–42 mm (**Table 67**).
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (**Table 67**) requires the use of multiple endoprostheses of different diameters.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.

Measurements to be taken during the pre-treatment assessment are described below (**Figure 9**):
A, B, C. Proximal aortic neck diameter (minimum of 1 cm apart)
D. Maximum lesion diameter
E, F, G. Distal aortic neck diameter (minimum of 1 cm apart)
H. Length of the lesion measured along the greater curvature of the flow lumen
I. Distance between the left subclavian / left common carotid artery and the proximal end of the lesion (minimum of 2 cm)
J. Distance between the distal end of the lesion and the celiac axis (minimum of 2 cm)
K. Total treatment length

Figure 9. Aortic Screening Measurements

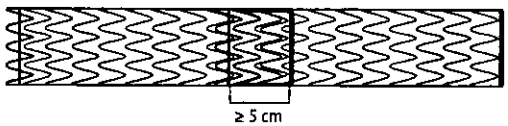


Using Multiple Devices

When multiple endoprostheses are used to compensate for aortic taper or treatment length, adhere to the sizing guide (**Table 67**) in conjunction with the recommended guidelines below:

- Overlapped endoprostheses should be one to two sizes different in diameter with an overlap of at least 3 cm (gold band to gold band) (**Figure 10**).
- Always deploy the larger diameter endoprosthesis into the smaller diameter endoprosthesis.
- If overlapping devices of the same diameter, overlap by at least 5 cm.
- Use of multiple devices with differing diameters requires a treatment length of ≥ 13 cm.

Figure 10. Overlap Region When Using Multiple Devices



Catheter Preparation and Arterial Access

1. Obtain appropriate vascular access, according to standard practice.
2. Administer heparin, according to standard practice.
3. Perform angiography to determine the correct placement location of the device, according to standard practice.
4. Advance the appropriate introducer sheath through the vasculature, according to standard practice.
5. Remove the GORE® TAG® Thoracic Endoprosthesis delivery catheter from the packaging, and examine for possible damage.
6. Flush heparinized saline through the flushing port. The delivery catheter is now ready for use.
7. Attach appropriate device cap onto the sheath if using the GORE® Introducer Sheath with Silicone Pinch Valve. If using the GORE® DrySeal Sheath, refer to product instructions for use.

GORE® TAG® Thoracic Endoprosthesis Deployment

1. Insert the endoprosthesis delivery catheter over a 0.035" (0.89 mm) 'super-stiff' guidewire, through the introducer sheath into the aorta. **Warning: Do not rotate the delivery catheter while device is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.**
2. Advance the endoprosthesis past the target location and pull back to desired position to release stored energy in the system.
3. Ensure the Image Intensifier (C-arm) is at the appropriate angle to visualize the landing zones. Clinicians recommend positioning the C-arm so that it is perpendicular to the neck, typically 45-75 degrees left anterior oblique (LAO) for the arch.
4. Position the endoprosthesis across the lesion using the radiopaque gold bands to identify the edges of the graft material (**Figure 2**). The end of the endoprosthesis, including the partially uncovered stent on the proximal end, should extend at least 20 mm into non-aneurysmal proximal and distal necks. Care should be taken not to cover the origin of any major arterial branches in the vicinity of the treatment area. **Warning: Do not rotate the delivery catheter outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.**
5. Ensure the device is positioned against the outer curve of the aorta using the guidewire.
6. Stabilize the introducer sheath at the patient and the delivery catheter at the introducer sheath to prevent introducer sheath or delivery catheter movement prior to or during deployment of the endoprosthesis. Loosen the luer lock on the deployment knob. While maintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a steady, continuous motion. Deployment initiates from the middle of the device and extends simultaneously to the proximal and distal ends.
7. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the endoprosthesis.
8. Additional endoprostheses may be deployed to treat longer segments. (Refer to *Using Multiple Devices* in the DIRECTIONS FOR USE section).

Completion of Procedure

1. After deployment, use the GORE® Tri-Lobe Balloon Catheter to smooth and seat the endoprosthesis against the aortic wall in the distal and proximal necks. Balloon the distal neck first, proximal neck second then overlap areas (if appropriate). Center the balloon at the radiopaque gold band on the endoprosthesis and inflate to the recommended volume (see GORE® Tri-Lobe Balloon Catheter Instructions for Use). Deflate the balloon, rotate the balloon approximately 60° and repeat the inflation. **Warning: If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.**
2. Perform arteriography in two views to assess exclusion of the lesion, luminal patency of the aorta, and endoprosthesis position.
3. Close arterial access site, according to standard practice.

IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

General

All patients should be advised this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging lesions) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms (e.g., pain, numbness, weakness).

Regular and consistent follow-up is a critical part of ensuring continuing safety and efficacy of aortic endovascular repair. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient. In the US clinical studies, at least one annual physician visit and the imaging schedule (**Table 68**) were employed.

Follow-up modalities include CT / CTA, and four-view (AP, lateral, 45° LAO and 45° RAO) chest x-ray. Data from these modalities is acquired and used to compare changes over time and their effects on exclusion of the lesion.

Table 68. Recommended Schedule for Patient Imaging Follow-Up

Schedule for Patient Imaging Follow-up			
Visit	**Angiogram**	**X-ray**	**CT Pre-Contrast and Contrast**
Pre-Treatment	X[1]		X[1]
Treatment (Pre and Post Deployment)	X		
Discharge		X	
1 Month		X	X
3 Month			X[2]
6 Month		X	X
12 Month (Annually Thereafter)		X	X

[1] Imaging should be performed < three months prior to the procedure

[2] Recommended if endoleak reported at one month

Angiographic Imaging

Angiographic images are recommended pre-treatment to evaluate the length and tortuosity of abdominal aorta, iliac and common femoral arteries.

- Images should include an angiographic marker catheter with incremental one centimeter markers over a 10-20 cm length.
- The following views are recommended for optimal evaluation and case planning:
  - Thoracic Chest; Supine-AP, Lateral, 45° LAO, and 45° RAO
  - Pelvis (to include bilateral common femorals); AP

Angiographic images are recommended during the treatment procedure both pre and post-deployment to evaluate device placement and orientation. Selective angiography during subsequent follow-up exams may provide useful device position and device integrity information.

CT / CTA Images

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and / or omission of CT images / film sets (non-consecutive) as it prevents precise anatomical and device comparisons over time.
- All images should include a scale for each image / film. Images should be arranged no smaller than 20:1 images on 14" x 17" sheets if film is used.
- **If an endoleak is suspected or there is lesion enlargement, it is recommended that non-contrast and contrast runs be performed.**
- Non-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.
- Clinical experience indicates that 3-D CTA reconstruction is the required imaging modality to accurately assess proximal and distal neck lengths for the GORE® TAG® Thoracic Endoprosthesis. These reconstructions should be performed in sagittal, coronal and varying oblique views depending upon individual patient anatomy. If 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.

Non-contrast and contrast enhanced baseline and follow-up exams are important for optimal patient surveillance. For the best results, use the following CT / CTA imaging guidelines listed in **Table 69**.

Table 69. CT / CTA Imaging Guidelines

CT Imaging Protocol	
Injection Volume (ml)	150
Injection Rate (cc/sec)	3-4 (through ≥ 20G IV)
Delay	SmarPrep1 or equivalent, 3 second delay
Start Position	Apices of lung (non-contrast), 2 cm above aortic arch
End Position	Superior Mesenteric Artery
Scan Diameter (FOV)	Large
DFOV (cm)	24
Scan Type	Helical
Rotation Speed (sec)	0.8
Slice Thickness (mm)	≤ 3
Scan Mode	HS
Table Speed (mm/rot)	15
Interval (mm)	2
[1] Baseline Location: Thoracic Aorta, ROI: Ascending Aorta, mA: 40, Monitor Delay: 10 s, Monitor ISD: 3 s Scan, Enhance Threshold: 100 HU, Scan Phase: 3 s	

Chest X-ray Film Series (plain film)

The following chest X-ray views are recommended for optimal visualization of the endoprosthesis.

- Supine – frontal (AP)
- Lateral
- 45° LPO
- 45° RPO

Ensure entire device is captured on each single image format lengthwise.

Set KvP to 75-85 to maximize device visualization.

If there is any concern about the device integrity (e.g., kinking, stent-wire breaks, relative component migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length including components) using 2-4x magnification.

MRI Information MR Conditional

Non-clinical testing has demonstrated that the GORE® TAG® Thoracic Endoprosthesis is MR Conditional. A patient with the GORE® TAG® Thoracic Endoprosthesis can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the Normal Operating Mode for 15 minutes of scanning (i.e., per pulse sequence). Testing to a maximum MR system reported whole-body-averaged SAR of 3.0 W/kg for 15 minutes of scanning has also been found to be safe.

MRI Related Heating

3.0 Tesla / 128 MHz

In non-clinical testing, the GORE® TAG® Thoracic Endoprosthesis produced a temperature rise of 1.9°C at an MR system reported maximum whole-body-averaged SAR of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst case location in a phantom designed to simulate human tissue. The whole-body-averaged SAR measured using calorimetry was 2.8 W/kg.

1.5 Tesla / 64 MHz

In non-clinical testing, the GORE® TAG® Thoracic Endoprosthesis produced a temperature rise of 1.8°C at an MR system reported maximum whole-body-averaged SAR of 2.8 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris/4 Software and placed in a worst case location in a phantom designed to simulate human tissue. The whole-body-averaged SAR measured using calorimetry was 1.5 W/kg.

Artifact

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for the GORE® TAG® Thoracic Endoprosthesis. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10 mm relative to the size and shape of the vascular device. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® TAG® Thoracic Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Lesions with type I endoleak
- Lesions with type III endoleak
- Lesion enlargement ≥ 5 mm increase in maximum diameter (regardless of endoleak status) compared to any previous measurement

WARNING: A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy, and the patient's personal choices. Patients should be counseled as to the possibility of subsequent reinterventions including catheter based and open surgical conversion.

WARNING: Strict adherence to the GORE® TAG® Thoracic Endoprosthesis IFU sizing guide (Table 67) is required when selecting the appropriate device size. The GORE® TAG® Thoracic Endoprosthesis is designed to be oversized from 6 to 33% which has been incorporated into the IFU sizing guide. Use outside the IFU sizing guide can result in endoleak, fracture, migration, device infolding or compression. DO NOT treat patients with the GORE® TAG® Device if their anatomical measurements do not fall within the IFU sizing guide requirements.

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- If device infolding or compression is observed, immediate conversion or other intervention to restore blood flow is essential.
- Adverse clinical outcomes including significant distal vascular ischemic complications (bowel ischemia, paraplegia) and / or death have resulted from device use outside of the IFU sizing guide.

DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event involving the GORE® TAG® Thoracic Endoprosthesis should be reported to W. L. Gore & Associates immediately. To report an event in the US, call (800.) 437.-8181. Outside the US, contact your local technical representative.

PATIENT TRACKING INFORMATION

In addition to these Instructions for Use, the GORE® TAG® Thoracic Endoprosthesis is packaged with a Device Tracking Form which US hospital staff are required to complete and forward to Gore for the purposes of tracking all patients who receive a GORE® TAG® Thoracic Endoprosthesis product (as required by US Federal Regulations).

DEFINITIONS

 Use By

 Caution

 Consult Instructions for Use

 Do Not Resterilize

 Do Not Reuse

 Catalogue Number

 Batch Code

 MR Conditional

 CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

 Sterile

 Sterilized using Ethylene Oxide

 Do Not Use if Package Is Damaged

 Keep Dry

 Store in a Cool Place

 Catheter Working Length

 Delivery Profile

 Guidewire Compatibility

 Manufacturer

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AQ3565-ML1

Manufacturer

W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86004 • USA
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

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